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(71) Applicant *(for all designated States except US)*: **SMITH & NEPHEW, PLC** [GB/GB]; 15 Adam Street, London WC2N 6LA (GB).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BLOTT, Patrick, Lewis** [GB/GB]; 16 HodsoW Fields, Barmby Moor, York YO42 4ER (GB). **GREEN, Clare** [GB/GB]; 3 Howden Lane, Crockey Hill, York YO19 4SW (GB). **MARTIN, Robin** [GB/GB]; 4 Forge Close, Wheldrake, York YO19 6GF (GB). **GREENER, Bryan** [GB/GB]; 9 Beck Close, Elvington, York YO41 4BG (GB). **HARTWELL, Edward, Yerbury** [GB/GB]; 3 Haven Garth, Brough, Hull HU15 1EP (GB). **LEE-WEBB, Julian** [GB/GB]; 37 Moor Lane, Copmanthorpe, York YO23 3TJ (GB). **NICOLINI, Derek** [GB/GB]; 38 Castle Rise, South Cave, Brough HU15 2ET (GB).

(74) Agent: **DRAGGETT, Peter, Thornton**; Smith & Nephew, York Science Park, Heslington, York YO10 5DF (GB).

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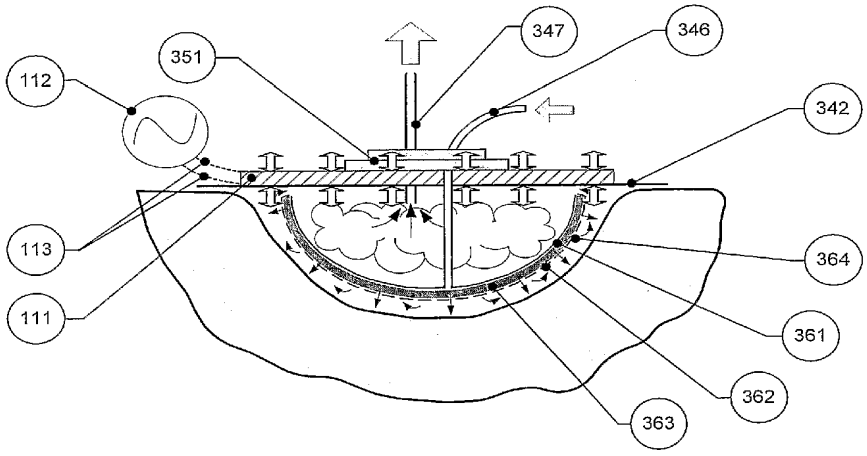

(57) Abstract: An apparatus for cleansing wounds with means for applying high frequency vibrational, in particular ultrasonic, energy to the wound bed, in which irrigant fluid from a reservoir connected to a conformable a wound dressing and wound exudate from the dressing are recirculated by a device for moving fluid through a flow path which passes through the dressing and a means for fluid cleansing and back to the dressing. The cleansing means (which may be a single-phase, e.g. micro-filtration, system or a two-phase, e.g. dialytic system) removes materials deleterious to wound healing, and the cleansed fluid, still containing materials that are beneficial in promoting wound healing, is returned to the wound bed. The means for applying high frequency vibrational, in particular ultrasonic, energy to the wound bed promotes wound healing. The dressing and a method of treatment using the apparatus.

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WOUND CLEANSING APPARATUS WITH ULTRASOUND

The present invention relates to apparatus and a medical wound dressing for irrigating, supplying high frequency vibrational, in particular ultrasonic, energy to and/or cleansing wounds, and a method of treating wounds using such apparatus for irrigating, supplying high frequency vibrational, in particular ultrasonic, energy to and/or cleansing wounds.

It relates in particular to such an apparatus, wound dressing and method that can be easily applied to a wide variety of, but in particular chronic, wounds, to cleanse them of materials that are deleterious to wound healing, whilst retaining materials that are beneficial in some therapeutic aspect, in particular to wound healing.

Before the present invention, aspirating and/or irrigating wounds and apparatus therefor were known, and tended to be used to remove wound exudate during wound therapy. In known forms of such wound therapy, the offtake from the wound, especially when in a highly exuding state, is voided to waste, e.g. to a collection bag.

Materials deleterious to wound healing are removed in this way.

However, materials that are beneficial in promoting wound healing, such as growth factors, naturally occurring anti-inflammatories, and other physiologically active components of the exudate from a wound are lost to the site where they can be potentially of most benefit, i.e. the wound bed, when such therapy is applied.

It thus would be desirable to provide a system of therapy which

a) can remove materials deleterious to wound healing from wound exudate, whilst retaining materials that are beneficial in promoting wound healing in contact with the wound bed, and/or
b) which allows fluids containing active amounts of materials that are beneficial in promoting wound healing to pass into and/or through the wound in contact with the wound bed.

Dialysis is a known method of treating bodily fluids such as blood ex vivo, to cleanse them of materials that are deleterious to the body systemically.

Retaining materials that are beneficial in some therapeutic aspect in the treated fluid is not an object of dialysis.

This method of treating bodily fluids is also a systemic therapy, since the treated fluid is returned to within the body. This is in contrast to a topical therapy in which the treated fluid is recycled outside the body, e.g. to a wound.

Dialysis also requires large amounts either of bodily fluids, such as blood, or of dialysate, and consequently the relevant devices tend not to be portable. Even when in a highly exuding state, chronic wounds produce relatively little fluid to be treated and relatively little materials that are beneficial in some therapeutic aspect to be retained in the wound and/or its environment.

It is an object of the present invention

a) to obviate at least some of the abovementioned disadvantages of known aspiration and/or irrigation therapy systems, and
b) to provide a system of therapy which
   i) can remove materials deleterious to wound healing from wound exudate, whilst retaining materials that are beneficial in promoting wound healing in contact with the wound bed, and/or
   ii) which allows fluids containing active amounts of materials that are beneficial in promoting wound healing to pass into and/or through the wound in contact with the wound bed.

It is a further object of the present invention

a) to obviate at least some of the abovementioned disadvantages of known dialysis systems, and
b) to provide a system of therapy which
   i) can remove materials deleterious to wound healing from wound exudate, whilst retaining materials that are beneficial in promoting wound healing in contact with the wound bed, and
   ii) further allows fluids containing active amounts of materials that are beneficial in promoting wound to pass into and/or through the wound in contact with the wound bed,

without affecting the body systemically.

It is a yet further object of the present invention

a) to obviate at least some of the abovementioned disadvantages of known dialysis systems, and
b) to provide a system of therapy which
   i) can remove materials deleterious to wound healing from wound exudate, whilst retaining materials that are beneficial in promoting wound healing in contact with the wound bed, and
   ii) further allows fluids containing active amounts of materials that are beneficial in promoting wound to pass into and/or through the wound in contact with the wound bed without affecting the body systemically, and
   iii) is portable.

Additionally, known forms of wound dressing and aspiration and/or irrigation therapy systems often create a wound environment under the backing layer that may result in the loss of optimum performance of the body's own tissue healing processes, and slow healing and/or in weak new tissue growth that does not have a strong three-dimensional structure adhering well to and growing from the wound bed. This is a significant disadvantage, in particular in chronic wounds.

High frequency vibrational, in particular ultrasonic, energy on and/or in a wound bed surface has been found to result in an improved breaking strength of tissue growth that has a strong three-dimensional structure adhering well to and growing from the wound bed, and reduction of wound recurrence.

High frequency vibrational, in particular ultrasonic, energy across the wound bed may also advantageously act against wound bacteria, by
a) breaking up biofilm growth before it develops a strong three-dimensional structure adhering well to and growing from the wound bed,
b) releasing them to be attacked by the body in the wound, and/or
c) breaking up the bacterial cell wall at higher intensities.

It may aid in the debridement of slough, eschar and necrotic tissue growth from the wound.

It is an object of the present invention

a) to obviate at least some of the abovementioned disadvantages of known wound dressing, and

b) to provide a system of therapy which

i) can remove materials deleterious to wound healing from wound exudate,whilst retaining materials that are beneficial in promoting wound healing in contact with the wound bed, and

ii) which creates high frequency vibrational, in particular ultrasonic, energy on and/or in a wound bed surface.

Thus, according to a first aspect of the present invention there is provided an apparatus for aspirating, irrigating and/or cleansing wounds, characterised in that it comprises

a) a fluid flow path, comprising

i) a conformable wound dressing, having

a backing layer which is capable of forming a relatively fluid-tight seal or closure over a wound and

at least one inlet pipe for connection to a fluid supply tube, which passes through and/or under the wound-facing face, and

and at least one outlet pipe for connection to a fluid offtake tube, which passes through and/or under the wound-facing face,

the point at which the or each inlet pipe and the or each outlet pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure over the wound,

at least one inlet pipe being connected to a fluid recirculation tube, and at least one outlet pipe being connected to a fluid offtake tube: and

ii) a means for fluid cleansing having at least one inlet port connected to a fluid offtake tube and at least one outlet port connected to a fluid recirculation tube;

b) a fluid reservoir connected by a fluid supply tube to an integer of the flow path (optionally or as necessary via means for flow switching between supply and recirculation);

c) a device for moving fluid through the wound dressing and means for fluid cleansing, and optionally or as necessary the fluid supply tube;

d) means for bleeding the flowpath, and

e) means for applying high frequency vibrational, in particular ultrasonic, energy to the wound bed;

such that fluid may be supplied to fill the flowpath from the fluid reservoir via the fluid supply tube (optionally or as necessary via the means for flow switching) and recirculated by the device through the flow path.
optionally or as necessary means for bleeding the offtake and/or recirculation tubes.

Where any pipe is described in connection with the apparatus as being connected or for connection to a (mating end of a) tube, e.g. a fluid supply tube, fluid recirculation tube or fluid offtake tube, the pipe and the tube may form a single integer in the flow path through which the circulating fluid from the wound passes.

The means for applying high frequency vibrational, in particular ultrasonic, energy to the wound bed via the irrigant fluid and/or wound exudate may be an high frequency vibrational, in particular ultrasonic, sonode and/or a component of the apparatus flow path connected to a sonode, the sonic conductivity of which is sufficient for it to function as an high frequency vibrational, in particular ultrasonic, conductor.

The source of the ultrasound field may be integral with the sonode, or it may be connected to it by means for an high frequency vibrational, in particular ultrasonic, connection, typically a sonically insulated but conductive waveguide.

The desired or optimum intensities and frequencies of such ultrasound across the wound bed for the stimulation of the healing of wounds will substantially determine

a) the position along the apparatus flow path or the component of the apparatus flow path where the means for applying high frequency vibrational, in particular ultrasonic, energy to the wound bed and/or conductively heated component of the apparatus flow path is mounted relative to the dressing;
b) the flow rate of irrigant fluid and/or wound exudate;
c) the intensity of ultrasound at the point of supply of energy to apparatus that is necessary given the level of energy loss in the system in which the fluid recirculates and energy is conducted to the wound; and/or

d) the nature of the ultrasound source.

Subject to the above, the means may be at any convenient or appropriate position or component of the apparatus flow path.

Examples include a means for applying high frequency vibrational, in particular ultrasonic, energy to the wound bed and/or conductively connected component of the apparatus flow path

a) mounted distally of the body on, in or inside of the dressing;
b) mounted in, on, at or near one or more of the fluid inlet pipe(s) and outlet pipe(s) that pass through and/or under the wound-facing face of the backing layer;
c) mounted in, on, at or near one or more of the connectors in the tubes that form the flow path of the apparatus;
d) mounted in, on, at or near the reservoir ; and/or
e) mounted in, on, at or near the means for fluid cleansing.

Often, the level of energy loss in the system in which the fluid recirculates and energy is conducted to the wound; and/or the nature of the ultrasound source. means that a convenient or appropriate position or component of the apparatus flow path for applying high frequency vibrational, in particular ultrasonic, energy to the wound bed and/or conductively connected component of the apparatus flow path is on, in or inside of the dressing and/or in, on, at or near one or more of the fluid inlet pipe(s) and outlet pipe(s) that pass through and/or under the wound-facing face of its backing layer.

In order to effectively deliver high-frequency vibrational, in particular ultrasonic, energy, as an energy field to the wound bed and/or the fluid thereover, there needs to be a suitably conductive bridge between the wound bed surface and the ultrasound sonode. Water is a good transfer medium of ultrasound, so the presence of a substantially continuous bridge of wound fluid and/or irrigant should provide adequate energy transfer.

Both longitudinal and shear waves generated by a transducer mechanism and/or shear waves generated by such longitudinally propagating waves provide effective healing of wounds.

All these types of waves may propagate directly to the wound. Topically applied longitudinal waves may also be reflected by underlying bone tissue and skin layers and these and shear waves generated by them propagate towards the wound for the healing thereof

The transducer should be arranged having an operating surface, with the transducer, disposed substantially adjacent to the wound to emit ultra sound to propagate in the direction of the wound for healing thereof.

The transducer may include an axis and a focusing element for focusing the propagation of the ultrasound at a predetermined angle with respect to the axis

The format of such transducers are described in detail in WO 99/56829, WO 99/48621 and US 5,904,659, all of which are incorporated herein by way of reference.

High frequency vibrational, in particular ultrasonic, energy, as is applied in the invention as an ultrasound field to the wound bed and/or the fluid thereover is characterised by parameters such as intensity, frequency, wave form and whether it is slow-pulsed either regularly or randomly on the overall ultrasound waveform.

Examples of suitable intensities of ultrasound applied include a spatial peak temporal average acoustic intensity between 5 - 100 mW/cm^2, e.g. 10 to 75 mW/cm^2, such as 30 to 50 mW/cm^2. When the ultrasound is slow-pulsed, this allows higher peak intensities.

Higher intensity ultrasound is more for hospital use, where relatively high intensities and/or pulsing can only be used safely with professional supervision, or for field hospital use.

Examples of suitable frequencies of ultrasound across the wound bed for the stimulation of the healing of wounds include in general an ultrasound carrier frequency between 20 kHz and 10 MHz, such as 60 kHz to 5 MHz, such as 200 kHz to 3 MHz.

Examples of suitable waveforms of ultrasound across the wound bed for the stimulation of the healing of such wounds include those described in detail in WO 99/56829, WO 99/48621 and US 5,904,659, all of which are incorporated herein by way of reference optionally slow-pulsed either regularly or randomly on the overall ultrasound waveform.

These may be optionally slow-pulsed either regularly or randomly on the overall vibrational waveform with a relatively low-frequency modulating signal.

Examples of suitable pulsing of ultrasound on/across the wound bed for the stimulation of the healing of wounds include pulsing at low frequencies such as 5 Hz to 10kHz.

Application may be made continuously or intermittently, for example 1-4 times daily for a period of 20 minutes per application.

As noted above, the apparatus for irrigating, supplying high frequency vibrational, in particular ultrasonic, energy to and/or cleansing wounds of the present invention is characterised in that it comprises at least one sonode for applying a vibrational field to the wound bed and/or the fluid thereover.

The source of the sound field may be connected to the sonode by means for an high frequency vibrational, in particular ultrasonic, connection, typically a sonically insulated but conductive waveguide, or it may be integral with or comprise it

In the former case, the source may be of any conventional type, e.g., in the case of ultrasound, a piezoelectric transducer; or others described in detail in WO 99/56829, WO 99/48621 and US 5,904,659, all of which are incorporated herein by way of reference.
Suitable materials for the sonode include materials that do not absorb high-frequency vibrational or ultrasonic energy, such as an Exogen ™ device.

Suitable materials for the waveguides include ultrasound-conductive materials such as those described in detail in WO 99/56829, WO 99/48621 and US 5,904,659, all of which are incorporated herein by way of reference.

Examples of instances where the sonode effectively is or is integral with the ultrasonic source, include a piezoelectric transducer directly attached to or integral with a component of the apparatus flow path.

Suitable materials for such a piezoelectric transducing sonode include those described in detail in WO 99/56829, WO 99/48621 and US 5,904,659, all of which are incorporated herein by way of reference.

These include synthetic polymeric materials such as certain halogenated polyolefins, such as fluorinated olefin polymers and copolymers, such as polyvinylidene fluoride and copolymers thereof.

Examples of suitable materials also include thermoplastics, and elastomers and elastomer blends, having for example particulate piezoelectric dispersed through it, such as the certain halogenated polyolefins, such as fluorinated olefin polymers and copolymers, such as polyvinylidene fluoride and copolymers thereof mentioned above; and certain minerals, such as quartz.

Examples of suitable such thermoplastics materials and elastomers and elastomer blends include synthetic polymeric materials that do not absorb aqueous fluids, such as
polyolefins, such as polyethylene e.g. high-density polyethylene, polypropylene, copolymers thereof, for example with vinyl acetate and polyvinyl alcohol, and mixtures thereof;
polysiloxanes;
polyesters, such as polycarbonates; polyamides, e.g. nylon 6 - 6 and 6 - 10, and hydrophobic polyurethanes.

They may be hydrophilic, and thus also include hydrophilic polyurethanes.
They also include thermoplastic elastomers and elastomer blends, for example copolymers, such as ethyl vinyl acetate, optionally or as necessary blended with high-impact polystyrene.

They further include elastomeric polyurethane, particularly polyurethane formed by solution casting.

Where the source is or includes a piezoelectric transducer, it will be electrically stimulated to change shape repeatedly as appropriate or desired at ultrasonic frequencies by an ultrasonic frequency electrical signal generator run at the appropriate frequencies.

The sonode or sonode-transducer may be mounted at any convenient or appropriate position or component of the apparatus flow path. Typically, however, as noted above, it is

a) mounted distally of the body on, in or inside of the dressing; and/or
b) mounted in, on, at or near one or more of the fluid inlet pipe(s) and outlet pipe(s) that pass through and/or under the wound-facing face of the backing layer.

It will be so positioned as to apply an ultrasound field to the fluid across the wound bed and/or to be in contact with the wound bed and/or the surrounding surfaces of the body. It may be more convenient if the sonode or sonode-transducer is outside the dressing, since otherwise it requires that a waveguide or electric leads will pass through and/or under the wound-facing face of the backing layer, and the point at which it passes or they through and/or under the wound-facing face must form a relatively fluid-tight seal or closure over the wound.

Where the sonode or sonode-transducer is mounted on the dressing, e.g. the backing layer, the wound dressing may then effectively be capable of being electrically stimulated to change shape repeatedly as appropriate or desired at high frequency vibrational, in particular ultrasonic, frequencies.

In all relevant embodiments of the present apparatus where the sonode or sonode-transducer is mounted distally of the body on, in or inside of the dressing, it will often be at or near the centre of the dressing backing layer.

It may be attached to or integral with it.

Where the sonode/transducer is mounted distally of the body on, in or inside of the dressing, it may be in the form of a relatively laminar integer, for example a discoidal pellet, foil, film, sheet or membrane.

It may be mounted to be clear of or surround one or more of the fluid inlet pipe(s) and outlet pipe(s) that pass through and/or under the wound-facing face of the backing layer.

The sonode or sonode-transducer may be attached, as appropriate by heat-sealing or by adhesive, or it may be a push, slide, snap or twist-lock fit.

For example, in the former case, a sonode-transducer such as a film, sheet or membrane of or comprising a piezoelectric transducing polyolefin, such as polyvinylidene fluoride and copolymers thereof, may be attached, e.g. by an adhesive, in particular a curable adhesive, coextrusion or heat lamination to the dressing.

It may be mounted distally on the backing layer to be clear of or surround one or more of the fluid inlet pipe(s) and outlet pipe(s) that pass through and/or under the wound-facing face of the backing layer.

Alternatively, it may be mounted proximally on the backing layer to be clear of, surround or pass across one or more of the fluid inlet pipe(s) and outlet pipe(s) that pass through and/or under the wound-facing face of the backing layer.

In the last case, it will have to be mounted on relatively stiff but still conformable, proximally projecting struts, supports, braces or stays, or on a similar proximally projecting boss to permit ingress or egress of fluid as appropriate.

Where the sonode or sonode-transducer is attached as a push, slide, snap or twist-lock fit, it may for example be mounted distally or proximally on the backing layer clear of the fluid inlet pipe(s) and outlet pipe(s) that pass through and/or under the wound-facing face of the backing layer, as a push fit in a (respectively) distally or proximally projecting recessed boss.

For example, a sonode such as an Exogen ™ device may be a push fit in a distally projecting recessed boss on the distal backing layer surface.

The sonode or is then connected ultrasonically to the dressing backing sheet by a layer of ultrasound coupling material, e.g. a coupling gel, which is needed to transmit the energy to the irrigant and/or exudate under the wound-facing face of the wound dressing.

A sonode-transducer, for example a disc, film, sheet or membrane, of or comprising a piezoelectric, such as polyvinylidene fluoride and copolymers thereof mentioned above, may be mounted at any convenient or appropriate position, in or inside of the dressing, as a push fit in a proximally projecting recessed boss.

Such a sonode/transducer does not need to be connected ultrasonically to the dressing backing sheet by a layer of ultrasound coupling material, e.g. the adhesive or by a coupling gel, which is needed to transmit the energy to the irrigant and/or exudate under the wound-facing face of the wound dressing.

However, it requires that electric leads pass through and/or under the wound-facing face of the backing layer, but the point at which they pass through the wound-facing face is not in contact with fluid, so that the closure over the wound is not prejudiced.

As noted above, the sonode or sonode-transducer may be mounted in, on, at or near one or more of the fluid inlet pipe(s) and outlet pipe(s) that pass through and/or under the wound-facing face of the backing layer,

In such case, the nature of the sonode or sonode-transducer, and the manner and position in which it may be mounted are similar to the those in the case of mounting in or on the dressing mutatis mutandis.

Mounting in, on, at or near one or more of the fluid inlet pipe(s) and outlet pipe(s) may however be less preferred than mounting on the backing layer at any convenient or appropriate position, since, because of the orientation of the pipes, it may be less easy to direct the high-frequency vibrational or ultrasonic energy sufficiently to achieve adequate therapeutic intensities across the wound bed for the stimulation of the healing of wounds.

Suitable dressings are depicted and described in more detail hereinafter.

As regards the flow path, the means for flow switching between supply and recirculation may take any form that enables the wound simultaneously to be

a) put into communication with the fluid reservoir but
b) closed to the fluid recirculation tube, and
c) vice versa.

Thus, if there is only one inlet pipe that passes through and/or under the wound-facing face of the wound dressing, the fluid reservoir is connected by the fluid supply tube to the flow path via means for flow switching as desired the into a fluid recirculation tube or a fluid offtake tube.

In this case, the means for flow switching between supply and recirculation may be a regulator, such as a T- valve. This is connected in turn to two parts of a fluid recirculation tube or a fluid offtake tube and the fluid supply tube, such that the desired flow switching between supply and recirculation is achieved.

If there are two or more inlet pipes, these may be connected respectively to a fluid supply tube or fluid recirculation tube, respectively having a first regulator and a second regulator, such as a valve or other control device for admitting fluids into the wound.

The desired flow switching between supply and recirculation is achieved by respectively having the first regulator open when the second regulator is shut, and vice versa.

The means for bleeding the flowpath may be situated in any appropriate part of the apparatus that is in contact with the irrigant and/or wound exudate, but is usually within the offtake and/or recirculation tubes. However, it is often as far downstream of and away from the reservoir and the fluid supply tube as possible, so that it may be used to prime the whole of the flowpath from the fluid reservoir via the fluid supply tube.

It may be a regulator, such as a valve or other control device, e.g. a T-valve that is turned to switch between bleed and recirculation, for bleeding fluids from the apparatus, e.g. to a waste reservoir, such as a collection bag.

Alternatively, flow switching between supply and recirculation may not be desired, but rather concomitant bleeding and/or recirculation is desired.

The latter may occur when the volume of irrigant and/or wound exudate in recirculation is increased by continuing addition to it of

a) wound exudate, and/or
b) fluid passing from a cleansing fluid through a selectively permeable integer, for example in a system such as a dialysis unit.

The means for bleeding the offtake and/or recirculation tubes may then be provided in the form of a regulator, such as a simple valve or other control device for admitting or blocking the passage of irrigant and/or exudate through a bleed line branching from the recirculation path.

The means for fluid cleansing may as desired be a 'single-phase system'.

In this, the circulating fluid from the wound and the fluid reservoir passes through a self-contained system in which materials deleterious to wound healing are removed and the cleansed fluid, still containing materials that are beneficial in promoting wound healing, is returned via the recirculation tube to the wound bed. Such systems are described in further detail hereinafter in connection with the means for fluid cleansing.

Alternatively, where appropriate it may be provided in the form of a two-phase system, such as a dialysis unit, or a biphasic liquid extraction unit.

In this, the circulating fluid from the wound and the fluid reservoir passes through a system in which the fluid recirculates in indirect or (less usually, direct) contact with a second fluid (dialysate) phase, more usually a liquid, in which materials deleterious to wound healing are removed and the cleansed fluid, still containing materials that are beneficial in promoting wound healing, is returned via the recirculation tube to the wound bed.

Such systems are described in further detail hereinafter in connection with the means for fluid cleansing.

In use, typically, the means for flow switching between supply and recirculation tubes is set to admit fluid into the wound from the fluid reservoir but to close the wound to the fluid recirculation tube.

Then, any means for bleeding the offtake and/or recirculation tubes are is opened and the device for moving fluid through the wound and means for fluid cleansing is started.

The capacity of the apparatus flow path and the flow rate of irrigant and/or wound exudate from the wound will largely determine whether it is appropriate to run the device to prime the apparatus throughout the whole length of the apparatus flow path, i.e. to displace any existing fluid reservoir (often air) from the fluid recirculation path, and for how long it should be run. Typically, there is a preponderance of irrigant from the fluid reservoir over wound exudate in recirculation, so that use of the device for moving fluid through the wound is appropriate for this purpose.

It is allowed to run until the apparatus is primed throughout the whole length of the apparatus flow path.

Then, typically the means for bleeding the offtake and/or recirculation tubes is closed, and the means for flow switching between supply and recirculation tubes is set to close the wound to the fluid reservoir but to admit fluid into the wound from the fluid recirculation tube.

If the means for fluid cleansing is a two-phase system, such as a dialysis unit, or a biphasic extraction unit, the cleansing fluid is typically set in motion in contact with the surface of the selectively permeable integer, for example the polymer film, sheet or membrane. Of course, the cleansing fluid may less usually be static, and then this step is omitted.

As noted below in more detail, the volume of irrigant and/or wound exudate from the wound in recirculation may be increased by continuing addition to it of

a) wound exudate, and/or

b) fluid passing from a cleansing fluid through a selectively permeable integer, for example the polymer film, sheet or membrane of a two-phase system, such as an dialysis unit.

Additionally or alternatively, it may be desired to apply a negative pressure to the wound by means of a device for moving fluid through the wound and means for fluid cleansing applied to the fluid in recirculation in the fluid recirculation tube downstream of and away from the wound dressing.

In such case, it may be desirable to provide a system in which concomitant bleeding and/or recirculation is possible, and to make the necessary adjustments to maintain the desired balance of fluid in recirculation by means of the means for bleeding the offtake and/or recirculation tubes.

The volume of irrigant and/or wound exudate from the wound in recirculation may be decreased by continuing loss from it of fluid passing from a cleansing fluid through a selectively permeable integer, for example in a system such as a dialysis unit.

Additionally or alternatively, it may be desired to apply a positive pressure to the wound by means of a device for moving fluid through the wound and means for fluid cleansing applied to the fluid in recirculation in the fluid recirculation tube upstream of and towards the wound dressing.

The means for flow switching between supply and recirculation may be similarly provided in a form in which concomitant supply and/or recirculation is possible, and to make the necessary adjustments to maintain the desired balance of fluid in recirculation by means of the means for flow switching.

It will be appreciated that where a positive or negative pressure is to be applied to the wound, at least one hollow body in the recirculation flow path to and from the wound bed should have sufficient resilience against the pressure to allow any significant compression or decompression of the irrigant fluid to occur.

In all embodiments of the apparatus, the type and material of such bodies (which are defined by a film, sheet or membrane) that are described by way of example herein to be suitable for use in the present invention will be largely capable of this function.

Thus, examples of suitable materials for bodies defined by a film, sheet or membrane, such as inlet or offtake and/or recirculation tubes and structures such as bags, chambers and pouches, filled with irrigant fluid, e.g. the backing layer of the wound dressing are suitably elastically resilient thermoplastic materials that are potentially capable of this function when pressure is applied in this way.

The present invention in this aspect provides several advantages.

One is that application of a positive pressure to the wound under the backing layer may make it possible to flood the tissue underlying the wound with one or more physiologically active components.

This may be effected in therapeutically active amounts, to promote greater wound healing than by treatment with the fluid physiologically active component(s) alone.

Such physiologically active components of the exudate that are beneficial to wound healing may be e.g. be enzymes or other species and may be supplied from the dialysate of a dialytic means for fluid cleansing.
It is believed that using the apparatus for aspirating, irrigating and/or cleansing wounds of the present invention cyclically the effects may be further enhanced.

Circulating wound fluid aids in movement of biological signalling molecules involved in wound healing to locations in the wound bed that are favourable to the wound healing process and/or to cells that would otherwise not be exposed to them, e.g. in a highly exuding wound.

This is especially the case in those embodiments of the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing wounds where there is an inlet or outlet manifold from which tubules radiate and run to the wound bed to end in openings that deliver and collect the fluid directly from the wound bed over an extended area.

Such materials include cytokines, enzymes, nutrients for wound cells to aid proliferation, oxygen, and other molecules that are beneficially involved in wound healing, such as growth factors, and others having beneficial effects (which may be further enhanced) in causing chemotaxis.

In all embodiments of the apparatus of this first aspect of the present invention for aspirating, irrigating and/or cleansing wounds, a particular advantage is the tendency of the wound dressing to conform to the shape of the bodily part to which it is applied.

The wound dressing comprises a backing layer with a wound-facing face which is capable of forming a relatively fluid-tight seal or closure over a wound and
at least one inlet pipe for connection to a fluid supply tube or recirculation tube, which passes through and/or under the wound-facing face, and
and at least one outlet pipe for connection to a fluid offtake tube, which passes through and/or under the wound-facing face,
the point at which the or each inlet pipe and the or each outlet pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure.

The term 'relatively fluid-tight seal or closure' is used herein to indicate one which is fluid- and microbe-impermeable and permits a positive or negative pressure of up to 50% atm., more usually up to 15% atm. to be applied to the wound. The term 'fluid' is used herein to include gels, e.g. thick exudate, liquids, e.g. water, and gases, such as air, nitrogen, etc.

The shape of the backing layer that is applied may be any that is appropriate to aspirating, irrigating and/or cleansing the wound across the area of the wound.

Examples of such include a substantially flat film, sheet or membrane, or a bag, chamber, pouch or other structure of the backing layer, e.g. of polymer film, which can contain the fluid.

The backing layer may be a film, sheet or membrane, often with a (generally uniform) thickness of up to 100 micron, preferably up to 50 micron, more preferably up to 25 micron, and of 10 micron minimum thickness.

Its largest cross-dimension may be up to 500 mm (for example for large torso wounds), up to 100 mm (for example for axillary and inguinal wounds), and up to 200 mm for limb wounds (for example for chronic wounds, such as venous leg ulcers and diabetic foot ulcers.

Desirably the dressing is resiliently deformable, since this may result in increased patient comfort, and lessen the risk of inflammation of a wound.

Suitable materials for it include synthetic polymeric materials that do not absorb aqueous fluids, such as
polyolefins, such as polyethylene e.g. high-density polyethylene, polypropylene, copolymers thereof, for example with vinyl acetate and polyvinyl alcohol, and mixtures thereof;
polysiloxanes;
polyesters, such as polycarbonates;
polyamides, e.g. nylon 6 - 6 and 6 - 10, and
hydrophobic polyurethanes.

They may be hydrophilic, and thus also include hydrophilic polyurethanes.

They also include thermoplastic elastomers and elastomer blends, for example copolymers, such as ethyl vinyl acetate, optionally or as necessary blended with high-impact polystyrene.

They further include elastomeric polyurethane, particularly polyurethane formed by solution casting.

Preferred materials for the present wound dressing include thermoplastic elastomers and curable systems.

The backing layer is capable of forming a relatively fluid-tight seal or closure over the wound and/or around the inlet and outlet pipe(s).

However, in particular around the periphery of the wound dressing, outside the relatively fluid-tight seal, it is preferably of a material that has a high moisture vapour permeability, to prevent maceration of the skin around the wound. It may also be a switchable material that has a higher moisture vapour permeability when in contact with liquids, e.g. water, blood or wound exudate. This may, e.g. be a material that is used in Smith & Nephew's Allevyn™, IV3000™ and OpSite™ dressings.

The periphery of the wound-facing face of the backing layer may bear an adhesive film, for example, to attach it to the skin around the wound.

This may, e.g. be a pressure-sensitive adhesive, if that is sufficient to hold the wound dressing in place in a fluid-tight seal around the periphery of the wound-facing face of the wound dressing.

Alternatively or additionally, where appropriate a light switchable adhesive could be used to secure the dressing in place to prevent leakage. (A light switchable adhesive is one the adhesion of which is reduced by photocuring. Its use can be beneficial in reducing the trauma of removal of the dressing.)

Thus, the backing layer may have a flange or lip extending around the proximal face of the backing layer, of a transparent or translucent material (for which it will be understood that materials that are listed above are amongst those that are suitable).

This bears a film of a light switchable adhesive to secure the dressing in place to prevent leakage on its proximal face, and a layer of opaque material on its distal face.

To remove the dressing and not cause excessive trauma in removal of the dressing, the layer of opaque material on the distal face of the flange or lip extending around the proximal wound is removed prior to application of radiation of an appropriate wavelength to the flange or lip.

If the periphery of the wound dressing, outside the relatively fluid-tight seal, that bears an adhesive film to attach it to the skin around the wound, is of a material that has a high moisture vapour permeability or is a switchable material, then the adhesive film, if continuous, should also have a high or switchable moisture vapour permeability, e.g. be an adhesive such as used in Smith & Nephew's Allevyn™, IV3000™ and OpSite™ dressings.

Where a vacuum, is applied to hold the wound dressing in place in a fluid-tight seal around the periphery of the wound-facing face of the wound dressing, the wound dressing may be provided with a silicone flange or lip to seal the dressing around the wound. This removes the need for adhesives and associated trauma to the patient's skin.

Where the interior of, and the flow of irrigant and/or wound exudate to and through, the dressing is under any significant positive pressure, which will tend to act at peripheral points to lift and remove the dressing off the skin around the wound.

In such use of the apparatus, it may thus be necessary to provide means for forming and maintaining such a seal or closure over the wound against such positive pressure on the wound, to act at peripheral points for this purpose.

Examples of such means include light switchable adhesives, as above, to secure the dressing in place to prevent leakage.

Since the adhesion of a light switchable adhesive is reduced by photocuring, thereby reducing the trauma of removal of the dressing, a film of a more aggressive adhesive may be used, e.g. on a flange, as above.

Examples of suitable fluid adhesives for use in more extreme conditions where trauma to the patient's skin is tolerable include ones that consist essentially of cyanoacrylate and like tissue adhesives, applied around the edges of the wound and/or the proximal face of the backing layer of the wound dressing, e.g. on a flange or lip.

Further suitable examples of such means include adhesive (e.g. with pressure-sensitive adhesive) and non-adhesive, and elastic and non-elastic

straps, bands, loops, strips, ties, bandages, e.g. compression bandages, sheets, covers, sleeves, jackets, sheathes, wraps, stockings and hose, e.g. elastic tubular hose or elastic tubular stockings that are a compressive fit over a limb wound to apply suitable pressure to it when the therapy is applied in this way; and inflatable cuffs, sleeves, jackets, trousers, sheathes, wraps, stockings and hose that are a compressive fit over a limb wound to apply suitable pressure to it when the therapy is applied in this way.

Such means may each be laid out over the wound dressing to extend beyond the periphery of the backing layer of the wound dressing, and as appropriate will be adhered or otherwise secured to the skin around the wound and/or itself and as appropriate will apply compression (e.g. with elastic bandages, stockings) to a degree that is sufficient to hold the wound dressing in place in a fluid-tight seal around the periphery of the wound,

Such means may each be integral with the other components of the dressing, in particular the backing layer.

Alternatively, it may be permanently attached or releasably attached to the dressing, in particular the backing layer, with an adhesive film, for example, or these components may be a Velcro ™, push snap or twist-lock fit with each other.

The means and the dressing may be separate structures, permanently unattached to each other.

In a more suitable layout for higher positive pressures on the wound, a stiff flange or lip extends around the periphery of the proximal face of the backing layer of the wound dressing as hereinbefore defined.

The flange or lip is concave on its proximal face to define a peripheral channel or conduit.

It has a suction outlet that passes through the flange or lip to communicate with the channel or conduit and may be connected to a device for applying a vacuum, such as a pump or a piped supply of vacuum.

The backing layer may be integral with or attached, for example by heat-sealing, to the flange or lip extending around its proximal face.

To form the relatively fluid-tight seal or closure over a wound that is needed and to prevent passage of irrigant and/or exudate under the periphery of the wound-facing face of the wound dressing, in use of the apparatus, the dressing is set on the skin around the wound.

The device then applies a vacuum to the interior of the flange or lip, thus forming and maintaining a seal or closure acting at peripheral points around the wound against the positive pressure on the wound.

With all the foregoing means of attachment, and means for forming and maintaining a seal or closure over the wound, against positive or negative pressure on the wound at peripheral points around the wound, the wound dressing sealing periphery is preferably of a generally round shape, such as an ellipse, and in particular circular.

To form the relatively fluid-tight seal or closure over a wound and around the inlet pipe(s) and outlet pipe(s) at the point at which they pass through and/or under the wound-facing face, the backing layer may be integral with these other components.

The components may alternatively just be a push, snap or twist-lock fit with each other, or adhered or heat-sealed together.

The or each inlet pipe or outlet pipe may be in the form of an aperture, such as a funnel, hole, opening, orifice, luer, slot or port for connection as a female member respectively to a mating end of
a fluid recirculation tube and/or fluid supply tube (optionally or as necessary via means for forming a tube, pipe or hose, or nozzle, hole, opening, orifice, luer, slot or port for connection as a male member respectively to a mating end of
a fluid recirculation tube and/or fluid supply tube (optionally or as necessary via means for flow switching between supply and recirculation) or
a fluid offtake tube.

Where the components are integral they will usually be made of the same material (for which it will be understood that materials that are listed above are amongst those that are suitable).

Where, alternatively, they are a push, snap or twist-lock fit, the may be of the same material or of different materials. In either case, materials that are listed above are amongst those that are suitable for all the components.

The or each pipe will generally pass through, rather than under the backing layer. In such case, the backing layer may often have a rigid and/or resiliently inflexible or stiff area to resist any substantial play between the or each pipe and the or each mating tube, or deformation under pressure in any direction.

It may often be stiffened, reinforced or otherwise strengthened by a boss projecting distally (outwardly from the wound) around each relevant tube, pipe or hose, or nozzle, hole, opening, orifice, luer, slot or port for connection to a mating end of a fluid recirculation tube and/or fluid supply tube or fluid offtake tube.

Alternatively or additionally, where appropriate the backing layer may have a stiff flange or lip extending around the proximal face of the backing layer to stiffen, reinforce or otherwise strengthen the backing layer.

The wound dressing may not comprise any integer under the backing layer in the wound in use.

However, this may not provide a system to distribute irrigant over a sufficient functional surface area to irrigate the wound at a practical rate. To be suitable for use, in particular in chronic wound dialysis, with relatively high concentrations of materials that are deleterious to wound healing, it may be advantageous to provide a system where wound irrigant and/or wound exudate may be distributed more evenly, or pass in a more convoluted path under the dressing over the wound bed.

Accordingly, one form of the dressing is provided with a 'tree' form of pipes, tubes or tubules that radiate from an inlet manifold to the wound bed to end

in apertures and deliver the circulating fluid directly to the wound bed via the apertures. Similarly, there is an outlet manifold from which tubules radiate and run to the wound bed to end in openings and collect the fluid directly from the wound bed.

The pipes, etc. may radiate regularly or irregularly through the wound in use, respectively from the inlet or outlet manifold, although regularly may be preferred.

A more suitable layout for deeper wounds is one in which the pipes, etc. radiate hemispherically and concentrically, to the wound bed.

For shallower wounds, examples of suitable forms of such layout of the pipes, etc. include ones in which the pipes, etc. radiate in a flattened hemiellipsoid and concentrically, to the wound bed.

Other suitable forms of layout of the pipes, etc. include one which have pipes, tubes or tubules extending from the inlet pipe(s) and/or outlet pipe(s) at the point at which they pass through and/or under the wound-facing face of the backing layer to run over the wound bed. These may have a blind bore with perforations, apertures, holes, openings, orifices, slits or slots along the pipes, etc.

These pipes, etc. then effectively form an inlet pipe manifold that delivers the circulating fluid directly to the wound bed or outlet pipe or collects the fluid directly from the wound respectively.

It does so via the holes, openings, orifices, slits or slots in the tubes, pipes, tubules, etc. over most of the wound bed under the backing layer.

It may be desirable that the tubes, pipes or tubules are resiliently flexible, e.g. elastomeric, and preferably soft, structures with good conformability in the wound and the interior of the wound dressing.

When the therapy is applied in this way, the layout of the tubes, pipes, tubules, etc. may depend on the depth and/or capacity of the wound.

Thus, for shallower wounds, examples of suitable forms of such layout of the tubes, pipes, tubules, etc. include ones that consist essentially of one or more of the tubes, etc in a spiral.

A more suitable layout for deeper wounds when the therapy is applied in this way may be one which comprises one or more of the tubes, etc in a helix or spiral helix.

Other suitable layouts for shallower wounds include one which have blind-bore, perforated inlet pipe or outlet pipe manifolds that circulate fluid in the wound when the dressing is in use.

One or both of these may be such a form, the other may be, e.g. one or more straight blind-bore, perforated radial tubes, pipes or nozzles.

Another suitable layout is one in which
an inlet pipe and/or outlet pipe manifold that delivers the circulating fluid directly to the wound bed or collects the fluid directly from the wound respectively
via inlet and/or outlet tubes, pipes or tubules,
and the inlet manifold and/or outlet manifold is formed by slots in layers permanently attached to each other in a stack, and
the inlet and/or outlet tubes, pipes or tubules are formed by apertures through layers permanently attached to each other in a stack. (In Figure 10a there is shown an exploded isometric view of such a stack, which is non-limiting.)

The presence of a manifold, such as

a) an open-celled or reticulated foam or
b) a hollow body defined by a film, sheet or membrane, such as a bag, chamber, pouch or other structure, containing a fluid,

should not substantially interfere with the transfer of ultrasound, since it contains an aqueous fluid, such as water, saline or other irrigant fluid and wound exudate.

However, multi-layer manifolds such as those described immediately above may absorb ultrasound energy to a significant extent, so that the position of the sonode may have to be adjusted to mitigate this effect.

As also mentioned herein, the backing layer that is applied may be any that is appropriate to the present system of therapy and permits a positive or negative pressure of up to 50% atm., more usually up to 25% atm. to be applied to the wound.

It is thus often a microbe-impermeable film, sheet or membrane, which is substantially flat, depending on any pressure differential on it, and often with a (generally uniform) thickness similar to such films or sheets used in conventional wound dressings.
That is, up to 100 micron, preferably up to 50 micron, more preferably up to 25 micron, and of 10 micron minimum thickness.

The backing layer may often have a rigid and/or resiliently inflexible or stiff area to resist any substantial play between other components that are not mutually integral, and may be stiffened, reinforced or otherwise strengthened, e.g. by a projecting boss.

Such a form of dressing would not be very conformable to the wound bed, and may effectively form a chamber, hollow or cavity defined by a backing layer and the wound bed under the backing layer.

It may be desirable that the interior of the wound dressing conform to the wound bed, even for a wound in a highly exuding state. Accordingly, one form of the dressing is provided with a wound filler under the backing layer.

This is favourably a resiliently flexible, e.g. elastomeric, and preferably soft, structure with good conformability to wound shape.

It is urged by its own resilience against the backing layer to apply gentle pressure on the wound bed.

The wound filler may be integral with the other components of the dressing, in particular the backing layer.

Alternatively, it may be permanently attached to them/it, with an adhesive film, for example, or by heat-sealing, e.g. to a flange or lip extending from the proximal face, so a not to disrupt the relatively fluid-tight seal or closure over the wound that is needed.

Less usually, the wound filler is releasably attached to the backing layer, with an adhesive film, for example, or these components may be a push, snap or twist-lock fit with each other.

The wound filler and the backing layer may be separate structures, permanently unattached to each other.

The wound filler may be or comprise a solid integer, favourably a resiliently flexible, e.g. elastomeric, and preferably soft, structure with good conformability to wound shape. Examples of suitable forms of such wound fillers are foams formed of a suitable material, e.g. a resilient thermoplastic. Preferred materials for the present wound dressing include reticulated filtration polyurethane foams with small apertures or pores.

Alternatively or additionally, it may be in the form of, or comprise one or more conformable hollow bodies defined by a film, sheet or membrane, such as a bag, chamber, pouch or other structure, filled with a fluid or solid that urges it to the wound shape.

The film, sheet or membrane, often has a (generally uniform) thickness similar to that of films or sheets used in conventional wound dressing backing layers.

That is, up to 100 micron, preferably up to 50 micron, more preferably up to 25 micron, and of 10 micron minimum thickness, and is often resiliently flexible, e.g. elastomeric, and preferably soft.

Such a filler is often integral with the other components of the dressing, in particular the backing layer, or permanently attached to them/it, with an adhesive film, for example, or by heat-sealing, e.g. to a flange

Examples of suitable fluids contained in the hollow body or bodies defined by a film, sheet or membrane include gases, such as air, nitrogen and argon, more usually air, at a small positive pressure above atmospheric; and liquids, such as water, saline.

Examples also include gels, such as silicone gels, e.g. CaviCare™ gel, or preferably cellulosic gels, for example hydrophilic cross-linked cellulosic gels, such as Intrasite ™ cross-linked materials. Examples also include aerosol foams, where the gaseous phase of the aerosol system is air or an inert gas, such as nitrogen or argon, more usually air, at a small positive pressure above atmospheric; and solid particulates, such as plastics crumbs.

The presence of a wound filler such as

a) an open-celled or reticulated foam or

b) a hollow body defined by a film, sheet or membrane, such as a bag, chamber, pouch or other structure, containing a fluid,

should not substantially interfere with the transfer of ultrasound provided it respectively

a) is saturated with an appropriate transfer medium (e.g. irrigant fluid and/or wound exudate), or

b) the hollow body defined by a film, sheet, etc contains an aqueous fluid, such as water, saline or a cellulosic gel, for example hydrophilic cross-linked cellulosic gels, such as Intrasite ™ cross-linked materials.

The presence of a gas-containing filler between ultrasound sonode and wound bed, e.g. an air bag, will prevent transfer of the ultrasound energy. In such cases the ultrasound sonode will have to be located in order to establish ultrasonic contact with the wound bed via a suitable transfer medium (e.g. it will be located under the air bag).

Of course, if the backing layer is a sufficiently conformable and/or e.g. an upwardly dished sheet, the backing layer may lie under the wound filler, rather than vice versa.

In this type of layout, in order for the wound filler to urge the wound dressing towards the wound bed, it will usually have to be firmly adhered or otherwise releasably attached to the skin around the wound.

This is especially the case in those embodiments where the wound filler and the backing layer are separate structures, permanently unattached to each other.

In such a layout for deeper wounds when the therapy is applied in this way, the means for such attachment may also form and maintain a seal or closure over the wound.

Where the filler is over the backing layer, and the fluid inlet pipe(s) and outlet pipe(s) pass through the wound-facing face of the backing layer, they may run through or around the wound filler over the backing layer.

One form of the dressing is provided with a wound filler under the backing layer that is or comprises a resiliently flexible, e.g. elastomeric, and preferably soft, hollow body defined by a film, sheet or membrane, such as a bag, chamber, pouch or other structure, with apertures, holes, openings, orifices, slits or slots, or tubes, pipes, tubules or nozzles. It communicates with at least one inlet or outlet pipe through at least one aperture, hole, opening, orifice, slit or slot.

The fluid contained in the hollow body may then be the circulating fluid in the apparatus.

The hollow body or each of the hollow bodies then effectively forms an inlet pipe or outlet pipe manifold that delivers the circulating fluid directly to the wound bed or collects the fluid directly from the wound respectively via the holes, openings, orifices, slits or slots, or the tubes, pipes or hoses, etc. in the film, sheet or membrane.

When the therapy is applied in this way, the type of the filler may also be largely determined by the depth and/or capacity of the wound.

Thus, for shallower wounds, examples of suitable wound fillers as a component of a wound dressing include ones that consist essentially of one or more conformable hollow bodies defining an inlet pipe and/or outlet pipe manifold that delivers the circulating fluid directly to the wound bed or collects the fluid directly from the wound.

A more suitable wound filler for deeper wounds when the therapy is applied in this way may be one which comprises one or more conformable hollow bodies defined by, for example a polymer film, sheet or membrane, that at least partly surround(s) a solid integer. This may provide a system with better rigidity for convenient handling.

Unless the wound filler under the backing layer effectively forms an inlet pipe or outlet pipe manifold, in order for good aspiration and/or irrigation of the wound bed to occur, it is appropriate for one or more bores, channels, conduits, passages, pipes, tubes, tubules and/or spaces, etc. to run

a) from the point at which the fluid inlet pipe(s) and outlet pipe(s) pass through and/or under the wound-facing face of the backing layer
b) through or around the wound filler under the backing layer.

Less usually, the wound filler is an open-cell foam with pores that may form such bores, channels, conduits, passages and/or spaces through the wound filler under the backing layer.

Where the filler is or comprises one or more conformable hollow bodies defined by, for example a polymer film, sheet or membrane, it may be provided with means for admitting fluids to the wound bed under the wound dressing.

These may be in the form of pipes, tubes, tubules or nozzles running from the point at which the fluid inlet pipe(s) and outlet pipe(s) pass through and/or under the wound-facing face of the backing layer through or around the wound filler under the backing layer.

All of the suitable layouts for shallower wounds that comprise blind-bore, perforated inlet pipe or outlet pipe manifolds that circulate fluid in the wound when the dressing is in use, that are described hereinbefore, may be used under a wound filler under the backing layer.

In brief, suitable layouts include ones where one or both manifolds are

annular or toroidal (regular, e.g. elliptical or circular, or irregular), optionally with blind-bore, perforated radial tubes, pipes or nozzles, branching from the annulus or torus; and/or

in a meandering, tortuous, winding, zigzag, serpentine or boustrophedic (i.e. in the manner of a ploughed furrow) pattern, or

defined by slots in and apertures through layers attached to each other in a stack.

The inlet and/or outlet tubes, the fluid recirculation tube and the fluid supply tube, etc. may be of conventional type, e.g. of elliptical or circular cross-section, and may suitably have a uniform cylindrical bore, channel, conduit or passage throughout their length.

Depending on the desired fluid volume flow rate of irrigant and/or wound exudate from the wound, and the desired amount in recirculation, suitably the largest cross-dimension of the bore may be up to 10 mm for large torso wounds, and up to 2 mm for limb wounds.

The tube walls should suitably thick enough to withstand any positive or negative pressure on them, in particular if the volume of irrigant and/or wound exudate from the wound in recirculation is increased by continuing addition to it of wound exudate, and/or fluid passing from a cleansing fluid through a selectively permeable integer, for example the polymer film, sheet or membrane of a two-phase system, such as an dialysis unit. However, as noted below with regard to pumps, the prime purpose of such tubes is to convey fluid irrigant and exudate through the length of the apparatus flow path, rather than to act as pressure vessels. The tube walls may suitably be at least 25 micron thick.

The bore or any perforations, apertures, holes, openings, orifices, slits or slots along the pipes, etc. or in the hollow body or each of the hollow bodies may be of small cross-dimension.

They may then effectively form a macroscopic and/or microscopic filter for particulates including cell debris and micro-organisms, whilst allowing proteins and nutrients to pass through.

Such tubes, pipes or hoses, etc. through and/or around the filler, whether the latter is a solid integer and/or one or more resiliently flexible or conformable hollow bodies, are described in further detail hereinbefore in connection with the inlet pipe(s) and outlet pipe(s).

The whole length of the apparatus for aspirating, irrigating and/or cleansing wounds should be microbe-impermeable once the wound dressing is over the wound in use.

It is desirable that the wound dressing and the interior of the apparatus for aspirating, irrigating and/or cleansing wounds of the present invention is sterile.

The fluid may be sterilised in the fluid reservoir and/or the rest of the system in which the fluid recirculates, including the means for fluid cleansing, by ultraviolet, gamma or electron beam irradiation. This way, in particular reduces or eliminates contact of internal surfaces and the fluid with any sterilising agent.

Examples of other methods of sterilisation of the fluid also include e.g. the use of

ultrafiltration through microapertures or micropores, e.g. of 0.22 to 0.45 micron maximum cross-dimension, to be selectively impermeable to microbes; and

fluid antiseptics, such as solutions of chemicals, such as chlorhexidine and povidone iodine; metal ion sources, such as silver salts, e.g. silver nitrate; and hydrogen peroxide;

although the latter involve contact of internal surfaces and the fluid with the sterilising agent.

It may be desirable that the interior of the wound dressing, the rest of the system in which the fluid recirculates, and/or the wound bed, even for a wound in a highly exuding state, are kept sterile after the fluid is sterilised in the fluid reservoir, or that at least naturally occurring microbial growth is inhibited.

Thus, materials that are potentially or actually beneficial in this respect may be added to the irrigant initially, and as desired the amount in recirculation increased by continuing addition.

Examples of such materials include antibacterial agents (some of which are listed above), and antifungal agents.

Amongst those that are suitable are, for example triclosan, iodine, metronidazole, cetrimide, chlorhexidine acetate, sodium undecylenate, chlorhexidine and iodine.

Buffering agents, such as potassium dihydrogen phosphate/ disodium hydrogen phosphate. may be added to adjust the pH, as may local analgesics/anaesthetics, such as lidocaine/lignocaine hydrochloride, xylocaine (adrenoline, lidocaine) and/or anti-inflammatories, to reduce wound pain or inflammation or pain associated with the dressing.

It is also desirable to provide a system in which physiologically active components of the exudate that are beneficial to wound healing are not removed before or after the application of fluid cleansing. This may occur, e.g. by the passive deposition of materials that are beneficial in promoting wound healing, such as proteins, e.g. growth factors. This may occur at any point at least one inlet or outlet pipe through at least one aperture, hole, opening, orifice, slit or slot.

The fluid contained in the hollow body may the deposition of materials that are beneficial in promoting wound healing, and consequent coating,

a) may be added to the irrigant initially, and as desired the amount in recirculation increased by continuing addition, or
b) may be used at any point or on any integer in the recirculation path in direct contact with the fluid, e.g. on the means for fluid cleansing or any desired tube or pipe.

Examples of coating materials for surfaces over which the circulating fluid passes include
anticoagulants, such as heparin, and
high surface tension materials, such as PTFE, and polyamides,

which are useful for growth factors, enzymes and other proteins and derivatives.

The apparatus of the invention for aspirating, irrigating and/or cleansing wounds is provided with means for admitting fluids directly or indirectly to the wound under the wound dressing in the form of a fluid supply tube to a fluid reservoir.

The fluid reservoir may be of any conventional type, e.g. a tube, bag (such as a bag typically used for blood or blood products, e.g. plasma, or for infusion feeds, e.g. of nutrients), chamber, pouch or other structure, e.g. of polymer film, which can contain the irrigant fluid.

The reservoir may be made of a film, sheet or membrane, often with a (generally uniform) thickness similar to that of films or sheets used in conventional wound dressing backing layers.

That is, up to 100 micron, preferably up to 50 micron, more preferably up to 25 micron, and of 10 micron minimum thickness.

It is often a resiliently flexible, e.g. elastomeric, and preferably soft, hollow body.

In all embodiments of the apparatus the type and material of the tubes throughout the apparatus of the invention for aspirating, irrigating and/or cleansing wounds and the fluid reservoir will be largely determined by their function.

To be suitable for use, in particular on chronic timescales, the material should be non-toxic and biocompatible, inert to any active components, as appropriate of the irrigant from the fluid reservoir and/or wound exudate in the apparatus flow path, and, in any use of a two-phase system dialysis unit, of the dialysate that moves into the circulating fluid in the apparatus.

When in contact with irrigant fluid, it should not allow any significant amounts of extractables to diffuse freely out of it in use of the apparatus.

It should be sterilisable by ultraviolet, gamma or electron beam irradiation and/or with fluid antiseptics, such as solutions of chemicals, fluid- and microbe-impermeable once in use, and flexible.

Examples of suitable materials for the fluid reservoir include synthetic polymeric materials, such as polyolefins, such as polyethylene, e.g. high-density polyethylene and polypropylene.

Suitable materials for the present purpose also include copolymers thereof, for example with vinyl acetate and mixtures thereof. Suitable materials for the present purpose further include medical grade poly(vinyl chloride).

Notwithstanding such polymeric materials, the fluid reservoir will often have a stiff area to resist any substantial play between it and components that are not mutually integral, such as the fluid supply tube towards the wound dressing, and may be stiffened, reinforced or otherwise strengthened, e.g. by a projecting boss.

The device for moving fluid through the wound and means for fluid cleansing may be any appropriate for this purpose, and may act at any appropriate point for this purpose.

It may apply a positive or negative pressure to the wound, although its prime purpose is to move fluid (irrigant from the fluid reservoir and/or wound exudate through the length of the apparatus flow path, rather than to apply a positive or negative pressure to the wound.

If applied to the fluid in recirculation in the fluid recirculation tube upstream of and towards the wound dressing and/or the fluid in the fluid supply tube towards the wound dressing (optionally or as necessary via means for flow switching between supply and recirculation), it will usually apply positive pressure (i.e. above-atmospheric pressure) to the wound bed.

Often the means for fluid cleansing is (most appropriately for its purpose) downstream of the wound dressing, and provides the highest resistance in the flow path.

This is especially the case where the means for fluid cleansing is a single-phase system, e.g. with ultrafiltration through microapertures or micropores, thus enhancing applied positive pressure to the wound.

Where the device is applied to the fluid in recirculation in the fluid recirculation tube and/or the fluid in the fluid offtake tube downstream of and away from the wound dressing, it will usually apply negative pressure (i.e. below-atmospheric pressure or vacuum) to the wound bed.

Again, often the means for fluid cleansing is (most appropriately for its purpose) downstream of the wound dressing, and provides the highest resistance in the flow path, thus enhancing applied negative pressure to the wound.

The following types of pump may be used as desired:

reciprocating pumps, such as:

shuttle pumps	- with an oscillating shuttle mechanism to move fluids at rates from 2 to 50 ml per minute;
diaphragm pumps	- where pulsations of one or two flexible diaphragms displace liquid while check valves control the direction of the fluid flow.
piston pumps	- where pistons pump fluids through check valves, in particular for positive and/or negative pressure on the wound bed;

rotary pumps, such as:

centrifugal pumps	
flexible impeller pumps	- where elastomeric impeller traps fluid between impeller blades and a moulded housing that sweeps fluid through the pump housing.
progressing cavity pumps	- with a cooperating screw rotor and stator, in particular for higher-viscosity and particulate-filled exudate;

rotary vane pumps - with rotating vaned disk attached to a drive shaft moving fluid without pulsation as it spins. The outlet can be restricted without damaging the pump.

peristaltic pumps - with peripheral rollers on rotor arms acting on a flexible circulation tube to urge fluid current flow in the tube in the direction of the rotor.

The type and/or capacity of the device will be largely determined by

a) the appropriate or desired fluid volume flow rate of irrigant and/or wound exudate from the wound, and

b) whether it is appropriate or desired to apply a positive or negative pressure to the wound bed, and the level of such pressure to the wound bed

for optimum performance of the wound healing process, and by factors such as portability, power consumption and isolation from contamination.

Such a device may also suitably be one that is capable of slow-pulsed, continuous, variable, reversible and/or automated and/or programmable fluid movement. It may in particular be a pump of any of these types.

In practice, even from a wound in a highly exuding state, such a rate of exudate flow is only of the order of up to 75 microlitres / cm^2/ hr (where cm^2 refers to the wound area), and the fluid can be highly mobile (owing to the proteases present). Exudate levels drop and consistency changes as the wound heals, e.g. to a level for the same wound that equates to 12.5 – 25 microlitres / cm^2 / hr.

Where materials deleterious to wound healing are removed by a two-phase system (see below.), such as a dialysis unit, fluid is also potentially lost to the system through the means for fluid cleansing.

This may occur, e.g. through a dialysis polymer film, sheet or membrane which is also permeable to water, in addition to materials deleterious to wound healing.

The balance of fluid in recirculation may thus further decrease, but may be adjusted to minimise this undesired loss in a routine manner as described hereinbefore.

Hence, it will be seen that the circulating fluid from the wound will typically contain a preponderance of irrigant over wound exudate in recirculation from the fluid reservoir.

The type and/or capacity of the device will thus be largely determined in this respect by the appropriate or desired fluid volume flow rate of irrigant, rather than that of exudate, from the wound.

In practice, such a rate of flow of total irrigant and/or wound exudate will be of the order of 1 to 1000, e.g. 3 to 300, and less preferably 1 to 10 ml / cm^2 / 24 hour, where the cm^2 refers to the wound area.

The volume of irrigant and/or wound exudate in recirculation may vary over a wide range, but will typically be e.g. 1 to 8 l. (for example for large torso wounds), 200 to 1500 ml (for example for axillary and inguinal wounds), and 0.3 to 300 ml for limb wounds when the therapy is applied in this way.

In practice, suitable pressures are of the order of up to 25% atm such as up to 10% atm. positive or negative pressure on the wound bed, the apparatus being operated as a closed recirculating system.

The higher end of these ranges are potentially more suitable for hospital use, where relatively high % pressures and/or vacua may be used safely under professional supervision.

The lower end is potentially more suitable for home use, where relatively high % pressures and/or vacua cannot be used safely without professional supervision, or for field hospital use.

The device may be a peristaltic pump or diaphragm pump, e.g. preferably a small portable diaphragm or peristaltic pump.

These are preferred types of pump, in order in particular to reduce or eliminate contact of internal surfaces and moving parts of the pump with (chronic) wound exudate, and for ease of cleaning.

It may suitably be one that applies positive pressure to the wound and/or the means for fluid cleansing. A preferred pump when the applied pressure is positive is a peristaltic pump, e.g. a small, portable peristaltic pump, mounted upstream of the means for fluid cleansing.

Where the pump is a peristaltic pump, this may be e.g. an Instech Model P720 miniature peristaltic pump, with a flow rate: of 0.2 – 180ml/hr and a weight of < 0.5 k. This is potentially useful for home and field hospital use.

Where the pump is a peristaltic pump, this may be e.g. an Instech Model P720 miniature peristaltic pump, with a flow rate: of 0.2 – 180ml/hr and a weight of < 0.5 k. This is potentially useful for home and field hospital use.

The pump may suitably be one that applies negative pressure to the wound and/or the means for fluid cleansing. A preferred pump when the applied pressure is negative is a diaphragm pump, e.g. a small, portable diaphragm pump, mounted downstream of the dressing or the means for fluid cleansing.

Where the pump is a diaphragm pump, and preferably a small portable diaphragm pump, the one or two flexible diaphragms that displace liquid may each be, for example a polymer film, sheet or membrane, that is connected to means for creating the pulsations. This may be provided in any form that is convenient, inter alia as a piezoelectric transducer, a core of a solenoid or a ferromagnetic integer and coil in which the direction of current flow alternates, a rotary cam and follower, and so on.

The outlet from the dressing passes to the means for fluid cleansing for removal of materials deleterious to wound healing from wound exudate, and in turn to the fluid recirculation tube(s).

The apparatus of the invention for aspirating, irrigating and/or cleansing wounds is provided with means for fluid cleansing, which may be

a) a single-phase system, such as an ultrafiltration unit, or a chemical adsorption unit; or
b) a two-phase system, such as a dialysis unit, or a biphasic extraction unit.

In the former, circulating fluid from the wound and the fluid reservoir passes through a self-contained system in which materials deleterious to wound healing are removed and the cleansed fluid, still containing materials that are beneficial in promoting wound healing are returned to the wound.

The single-phase system may be of any conventional type.

Examples of the means for fluid cleansing in such a system include a macro- or microfiltration unit, which appropriately comprises one or more macroscopic and/or microscopic filters.

These are to retain particulates, e.g. cell debris and micro-organisms, allowing proteins and nutrients to pass through.

Alternatively, they also include an ultrafiltration unit, such as a one in which the cleansing integer is a filter for materials deleterious to wound healing, for example a high throughput, low protein-binding polymer film, sheet or membrane which is selectively impermeable to materials deleterious to wound healing, which are removed and the cleansed fluid, still containing materials that are beneficial in promoting wound healing is passed by it.

The membrane may preferably be of a hydrophilic polymeric material, such as a cellulose acetate – nitrate mixture, polyvinylidene chloride, and, for example hydrophilic polyurethane.

Examples of less preferred materials include hydrophobic materials also including polyesters, such as polycarbonates, PTFE, and polyamides, e.g. 6-6 and 6 - 10, and hydrophobic polyurethanes, and quartz and glass fibre.

It has microapertures or micropores, the maximum cross-dimension of which will largely depend on the species that are to be selectively removed in this way and those to which it is to be permeable.

The former may be removed with microapertures or micropores, e.g. typically with a maximum cross-dimension in the range of 20 to 700 micron, e.g. 20 to 50 nm (for example for undesired proteins), 50 to 100 nm, 100 to 250 nm, 250 to 500 nm and 500 to 700 nm.

The filter integer may be a flat sheet or a membrane of a polymeric material in a more convoluted form, e.g. in the form of elongate structure, such as pipes, tubules, etc.

The system may be a chemical absorption and/or adsorption unit, for example one in which a particulate, such as a zeolite, or a layer, e.g. of a functionalised polymer has sites on its surface that are capable of removing materials deleterious to wound healing on passing the circulating fluid from the wound and the fluid reservoir over them.

The materials may be removed, e.g. by destroying or binding the materials that are deleterious to wound healing, by, for example chelators and/or ion exchangers, degraders, which may be enzymes.

Examples of such also include less specific chemical absorption and/or adsorption units, for example one in which a physical absorbent, such as activated carbon or a zeolite, has non-specific sites on its surface that are capable of removing materials deleterious to wound healing on passing the circulating fluid from the wound and the fluid reservoir over them.

The cleansing integer, for example the polymer film, sheet or other chemical absorption and/or adsorption means, etc should of course be capable of removing materials deleterious to wound healing at a practical rate for a given capacity of the apparatus flow path and the flow rate of irrigant.

In the two-phase system, circulating fluid from the wound and the fluid reservoir in indirect or (less usually, direct) contact with a second fluid (dialysate) phase, more usually a liquid.

Thus, in one form, a biphasic liquid extraction unit, the second fluid phase is (usually) a liquid that is immiscible with the circulating fluid from the dressing, over a surface of which the circulating fluid passes in direct contact with the cleansing fluid. Materials deleterious to wound healing are removed into the dialysate, and the cleansed fluid, still containing materials that are beneficial in promoting wound healing, is returned via the recirculation tube to the wound bed.

Examples of such means for fluid cleansing include those wherein the second fluid (dialysate) phase is perfluorodecalin and like materials

Alternatively, where appropriate it may be provided in a form in which the two fluids (recirculation fluid and dialysate) are separated by a significantly two-dimensional integer, for example a polymer film, sheet or membrane or hollow fibre or filament that is permeable to materials in the circulating fluid in the apparatus.

Again, materials deleterious to wound healing are removed into the dialysate, and the cleansed fluid, still containing materials that are beneficial in promoting wound healing, is returned via the recirculation tube to the wound bed.

In either form in which the two-phase system, such as a dialysis unit, is provided, in use typically the dialysate moves past the circulating fluid in the apparatus in a co- or preferably counter-current direction.

Pumps, such as peristaltic pumps, and/or valves control the direction of the two fluid flows.

However, the cleansing fluid may less usually be static, although this may not provide a system with sufficient (dynamic) surface area to remove materials deleterious to wound healing from wound exudate at a practical rate.

Typical dialysate flow rates in a dialytic means for fluid cleansing in the present apparatus for aspirating, irrigating and/or cleansing wounds are those used in the conventional type of two-phase system, such as a dialysis unit for systemic therapy.

The integer may be a film, sheet or membrane, often of the same type, and of the same (generally uniform) thickness, as those used in conventional two-phase system, such as a dialysis unit for systemic therapy.

The film, sheet or membrane may be substantially flat, and depending on any pressure differential across it may require other materials on or in it to stiffen, reinforce or otherwise strengthen it.

However, this may not provide a system with sufficient functional surface area to remove materials deleterious to wound healing from wound exudate at a practical rate.

To be suitable for use, in particular in chronic wound dialysis, with relatively high concentrations of materials that are deleterious to wound healing, it may be advantageous to provide a system in which the film, sheet or membrane of a polymeric material is in a more convoluted form.

This may be in the form of elongate structures, such as pipes, tubes hollow fibres or filaments or tubules of a round cross-section, e.g. elliptical or circular, e.g. in a parallel array with spaces therebetween.

The wound irrigant and/or wound exudate may recirculate through the inside and the cleansing fluid may pass into the spaces between adjacent pipes, tubes or tubules in a co- or preferably counter-current direction, or vice versa.

Again, materials deleterious to wound healing are removed into the dialysate, and the cleansed fluid, still containing materials that are beneficial in promoting wound healing, is returned via the recirculation tube to the wound.

Where the means for fluid cleansing is a two-phase system, e.g. in the form of a dialysis unit, or a biphasic extraction unit, the circulating fluid from the wound and the fluid reservoir passes across one surfaces of a significantly two-dimensional integer, for example a polymer film, sheet or membrane which is selectively permeable to materials deleterious to wound healing.

These are removed by passing a cleansing fluid across the other surface of the integer. The integer may be a film, sheet or membrane that is selectively permeable to the foregoing materials deleterious to wound healing.

These as above include
oxidants, such as free radicals, e.g. peroxide and superoxide;
iron II and iron III;
all involved in oxidative stress on the wound bed;
proteases, such as serine proteases, e.g. elastase, trypsin; chymotrypsin and thrombin; cysteine protease inhibitors; matrix metalloproteases, e.g. collagenase; and carboxyl (acid) proteases;
endotoxins, such as lipopolysaccharides;
autoinducer signalling molecules, such as homoserine lactone derivatives, e.g. oxo-alkyl derivatives;
inhibitors of angiogenesis such as thrombospondin-1 (TSP-1), plasminogen activator inhibitor, or angiostatin (plasminogen fragment);
pro-inflammatory cytokines such as tumour necrosis factor alpha (TNFα) and interleukin 1 beta (IL-1β); and
inflammatories, such as lipopolysaccharides, and e.g. histamine.

Examples of suitable materials for the film, sheet or membrane (typically in the form of conformable hollow bodies defined by the film, sheet or membrane, such as the structures described hereinbefore) include natural and synthetic polymeric materials.

The membrane may be of one or more hydrophilic polymeric materials, such as a cellulose derivative, e.g. regenerated cellulose, a cellulose mono-, di- or tri- esters, such as cellulose mono-, di- or tri-acetate, benzyl cellulose and Hemophan, and mixtures thereof.

Examples of other materials include hydrophobic materials, such as aromatic polysulphones, polyethersulphones, polyetherether-sulphones, polyketones, polyetherketones and polyetherether-ketones, and sulphonated derivatives thereof, and mixtures thereof.

Examples of other materials include hydrophobic materials, such as polyesters, such as polycarbonates and polyamides, e.g. 6-6 and 6 – 10; polyacrylates, including, e.g. poly(methyl methacrylate), polyacrylonitrile and copolymers thereof, for example acrylonitrile - sodium metallosulphonate copolymers; and poly(vinylidene chloride).

Suitable materials for the present membranes include thermoplastic polyolefins, such as polyethylene e.g. high-density polyethylene, polypropylene, copolymers thereof, for example with vinyl acetate and polyvinyl alcohol, and mixtures thereof.

The dialysis membrane should have a molecular weight cut off (MWCO) chosen to allow selective perfusion of species deleterious to wound healing that have been targeted for removal from the wound. For example, perfusion of the serine protease elastase (molecular weight 25900 Dalton) would require a membrane with MWCO >25900 Dalton. The MWCO threshold can be varied to suit each application between 1 and 3000000 Dalton.

Preferably, the MWCO should be as close as possible to this weight to exclude interference by larger competitor species.

For example, such a membrane with MWCO >25900 Dalton does not allow any significant amounts of the antagonist to elastase, alpha-1-antitrypsin (AAT) (molecular weight 54000 Dalton), which occurs naturally in wounds, to diffuse freely out of the wound fluid into the dialysate. The inhibitor, which is beneficial in promoting chronic wound healing, remains in contact with the wound bed, and can act beneficially on it, whilst the elastase that is deleterious to wound healing is removed.

Such use of the present apparatus is, e.g. favourable to the wound healing process in chronic wounds, such as diabetic foot ulcers, and especially decubitus pressure ulcers.

As noted hereinafter, antagonists, for example degrading enzymes, or sequestrating agents for elastase on the dialysate side of the membrane, may be used to enhance the removal of this protease from wound exudate.

Where it is desired to remove several different materials that are deleterious to wound healing, it may be advantageous to provide a system of modules in series, each of which removes a different material. This allows incompatible cleansing materials to be used on the same fluid and/or wound exudates.

Preferably any such system is a conventional automated, programmable system which can cleanse the wound irrigant and/or wound exudate with minimal supervision.

As noted above in more detail, fluid passes from a cleansing fluid through a selectively permeable integer.

This may be the typical permeable polymer film, sheet or membrane of a two-phase system, such as a dialysis unit.

Additionally, solutes or disperse phase species will pass from the dialysate into the irrigant and/or wound exudate through the dialysis polymer film, sheet or membrane.

This property may be used to perfuse materials beneficial to wound healing into the irrigant and/or exudate from a dialysate.

In this less conventional type of infusion feed, a broad spectrum of species will usually pass into the exudate and/or irrigant fluid from the dialysate.

These include
ionic species, such as bicarbonate;
vitamins, such as ascorbic acid (vitamin C) and vitamin E, and stable derivatives thereof, and mixtures thereof; to relieve oxidative stress on the wound bed;
pH buffering agents, such as potassium dihydrogen phosphate/ disodium hydrogen phosphate,
local analgesics/anaesthetics, such as lidocaine/lignocaine hydrochloride and xylocaine (adrenoline lidocaine) and/or anti-inflammatories, to reduce wound pain or inflammation or pain associated with the dressing

nutrients to aid proliferation of wound cells, such as amino acids, sugars, low molecular weight tissue building blocks and trace elements; and other cell culture medium species; and
gases, such as air, nitrogen, oxygen and/or nitric oxide.

For the purposes of fluid cleansing in the apparatus of the present invention, both the single-phase system and two-phase system may have captive (non-labile, insoluble and/or immobilised) species such as the following, bound to an insoluble and/or immobilised substrate.

The irrigant and/or wound exudate from the wound dressing passes over and/or through these materials and then in turn to the fluid recirculation tube(s).

Such materials include:
antioxidants and free radical scavengers, such as 3-hydroxytyramine (dopamine), ascorbic acid (vitamin C), vitamin E and glutathione, and stable derivatives thereof, and mixtures thereof; to relieve oxidative stress on the wound bed;
metal ion chelators and/or ion exchangers, such as transition metal ion chelators, such as iron III chelators (Fe III is involved in oxidative stress on the wound bed.), such as desferrioxamine (DFO), 3-hydroxytyramine (dopamine);
iron III reductants;
protease inhibitors, such as TIMPs and alpha 1-antitrypsin (AAT); serine protease inhibitors, such as 4-(2-aminoethyl)-benzene sulphonyl fluoride (AEBSF, PefaBloc) and Nα-*p*-tosyl-L-lysine chloro-methyl ketone (TLCK) and ε-aminocaproyl-*p*-chlorobenzylamide; cysteine protease inhibitors; matrix metalloprotease inhibitors; and carboxyl (acid) protease inhibitors;
sacrificial redox materials that are potentially or actually beneficial in promoting wound healing, by the removal of materials that trigger the expression into wound exudate of redox-sensitive genes that are deleterious to wound healing;
autoinducer signalling molecule degraders, which may be enzymes; and
anti-inflammatory materials to bind or destroy lipopolysaccharides, e.g. peptidomimetics

Other physiologically active components of the exudate that are deleterious to wound healing may be removed in this way.

These may be removed with suitable chelators and/or ion exchangers, degraders, which may be enzymes, or other species.

The following types of functionalised substrate has sites on its surface that are capable of removing materials deleterious to wound healing on passing the circulating fluid from the wound and the fluid reservoir over them:

heterogeneous resins , for example silica-supported reagents such as:
metal scavengers,
3-(diethylenetriamino)propyl-functionalised silica gel
2-(4-(ethylenediamino)benzene)ethyl-functionalised silica gel
3-(mercapto)propyl-functionalised silica gel
3-(1-thioureido)propyl-functionalised silica gel
triamine tetraacetate-functionalised silica gel

or electrophilic scavengers,
4-carboxybutyl-functionalised silica gel
4-ethyl benzenesulfonyl chloride-functionalised silica gel
propionyl chloride-functionalised silica gel
3-(isocyano)propyl-functionalised silica gel
3-(thiocyano)propyl-functionalised silica gel
3-(2-succinic anhydride)propyl-functionalised silica gel
3-(maleimido)propyl-functionalised silica gel

or nucleophilic scavengers,
3-aminopropyl-functionalised silica gel
3-(ethylenediamino)-functionalised silica gel
2-(4-(ethylenediamino)propyl-functionalised silica gel
3-(diethylenetriamino)propyl-functionalised silica gel
4-ethyl-benzenesulfonamide-functionalised silica gel
2-(4-toluenesulfonyl hydrazino)ethyl-functionalised silica gel
3-(mercapto)propyl-functionalised silica gel
dimethylsiloxy-functionalised silica gel
or base or acid scavengers,
3-(dimethylamino)propyl-functionalised silica gel

3-(1,3,4,6,7,8-hexahydro-2H-pyrimido-[1,2-α]pyrimidino)propyl-functionalised silica gel
3-(1-imidazol-1-yl)propyl-functionalised silica gel
3-(1-morpholino)propyl-functionalised silica gel
3-(1-piperazino)propyl-functionalised silica gel
3-(1-piperidino)propyl-functionalised silica gel
3-(4,4'-trimethyldipiperidino)propyl-functionalised silica gel
2-(2-pyridyl)ethyl-functionalised silica gel
3-(trimethylammonium)propyl-functionalised silica gel

or the reagents,
3-(1-cyclohexylcarbodiimido)propyl-functionalised silica gel
TEMPO-functionalised silica gel
2-(diphenylphosphino)ethyl-functionalised silica gel
2-(3,4-cyclohexyldiol)propyl-functionalised silica gel
3-(glycidoxy)propyl-functionalised silica gel
2-(3,4-epoxycyclohexyl)propyl-functionalised silica gel
1-(allyl)methyl-functionalised silica gel
4-bromopropyl-functionalised silica gel
4-bromophenyl-functionalised silica gel
3-chloropropyl-functionalised silica gel
4-benzyl chloride-functionalised silica gel
2-(carbomethoxy)propyl-functionalised silica gel
3-(4-nitrobenzamido)propyl-functionalised silica gel
3-(ureido)propyl-functionalised silica gel

or any combinations of the above.

The use of such captive (non-labile, insoluble and/or immobilised) species, such as the foregoing, bound to an insoluble and immobilised) substrate over and/or through which the irrigant and/or wound exudate from, the wound dressing passes has been described hereinbefore as suitable for the means for fluid cleansing.

However, they may additionally, where appropriate, be used in any part of the apparatus that is in contact with the irrigant and/or wound exudate, but often within the dressing, for removal of materials deleterious to wound healing from wound.

The means for fluid cleansing may additionally, where appropriate, comprise one or more macroscopic and/or microscopic filters.

These are to retain particulates, e.g. cell debris and micro-organisms, allowing proteins and nutrients to pass through.

Alternatively, a less conventional type of two-phase system (see above), such as a dialysis unit, may be used as the means for fluid cleansing. In this type, the dialysis polymer film, sheet or membrane is not an integer selectively permeable to materials deleterious to wound healing, such as
proteases, such as serine proteases, e.g. elastase, ~~trypsin; chymotrypsin~~ and thrombin; cysteine protease inhibitors; matrix metalloproteases, e.g. collagenase; and carboxyl (acid) proteases;
endotoxins , such as lipopolysaccharides;
inhibitors of angiogenesis such as thrombospondin-1 (TSP-1), Plasminogen activator inhibitor, or angiostatin (plasminogen fragment);
pro-inflammatory cytokines such as tumour necrosis factor alpha (TNFα) and interleukin 1 beta (IL-1β);
oxidants, such as free radicals, e.g. , e.g. peroxide and superoxide;
metal ions, e.g. iron II and iron III;
all involved in oxidative stress on the wound bed.

It will however also permit components of the exudate from a wound and/or irrigant fluid that may be larger or smaller molecules, but are beneficially involved in wound healing to pass into and through it.

In the dialysate, or preferably in one or more solid structural integers with at least one surface in contact with the dialysate, in the means for fluid cleansing, there are one or more materials that can remove materials deleterious to wound healing from wound exudate, by being

antagonists to such species, for example enzymes or others, such as protease inhibitors, such as serine protease inhibitors, such as 4-(2-aminoethyl)-benzene sulphonyl fluoride (AEBSF, PefaBloc) and Nα-*p*-tosyl-L-lysine chloromethyl ketone (TLCK) and ε-aminocaproyl-*p*-chlorobenzylamide; cysteine protease inhibitors; matrix metalloprotease inhibitors; and carboxyl (acid) protease inhibitors;

binders and/or degraders, such as anti-inflammatory materials to bind or destroy lipopolysaccharides, e.g. peptidomimetics;

anti-oxidants, such as 3-hydroxytyramine (dopamine), ascorbic acid (vitamin C), vitamin E and glutathione, and stable derivatives thereof, and mixtures thereof; to relieve oxidative stress on the wound bed;

chelators and/or ion exchanges, such as desferrioxamine (DFO), 3-hydroxytyramine (dopamine);

They further include peptides (including cytokines, e.g. bacterial cytokines, such as α-amino-γ-butyrolactone and L-homocarnosine); and

sacrificial redox materials that are potentially or actually beneficial in promoting wound healing, such as iron III reductants;

regeneratable materials of this type, such as glutathione redox systems; and other physiologically active components.

In use of the two-phase system dialysis unit, of this less conventional type, a broad spectrum of species will usually pass into the dialysate from the exudate.

Some (mainly ionic) species will pass from the dialysate into the irrigant and/or wound exudate through the dialysis polymer film, sheet or membrane that is not very selectively permeable to materials deleterious to wound healing.

The components of the exudate from a wound and/or irrigant fluid will diffuse freely to and fro through it.

If (preferably) none of the dialysate is voided to waste, e.g. to a collection bag, a steady state concentration equilibrium is eventually set up between the dialysate and the irrigant and/or wound exudate, which is 'topped up' from the wound dressing.

Circulating wound fluid aids in the quicker attainment of this equilibrium of materials beneficial in promoting wound healing.

It also returns them to the site where they can be potentially of most benefit, i.e. the wound bed.

The target materials deleterious to wound healing also pass into the dialysate from the exudate through the dialysis polymer film, sheet or membrane that is not very selectively permeable to materials deleterious to wound healing.

Unlike the other components of the exudate from a wound and/or irrigant fluid, the target materials deleterious to wound healing come into contact with the dialysate, or preferably with one or more solid structural integers with at least one surface in the dialysate, and are removed by the appropriate antagonists, binders and/or degraders, chelators and/or ion exchangers and redox agents, etc. The cleansed fluid, still containing some materials that are beneficial in promoting wound healing, is returned to the recirculation tube.

Unlike the other components of the exudate from a wound and/or irrigant fluid the target materials are constantly removed from the dialysate, very little of these species will pass from the dialysate into the irrigant and/or wound exudate, and a steady state concentration equilibrium is not set up, even if the species are constantly 'topped up' from the wound dressing.

It is believed that circulating wound fluid aids in removal from recirculation of the materials deleterious to wound healing from wound exudate, whilst retaining materials that are beneficial in promoting wound healing in contact with the wound.

A particular advantage of this form of the two-phase system, is that where a material that can remove materials deleterious to wound healing from wound exudate is (cyto)toxic or bioincompatible, or not inert to any components that are beneficial in promoting wound healing, the system does not allow any significant amounts of antagonist to diffuse freely out of the dialysate into the irrigant fluid. The active material can act beneficially on the fluid however.

The film sheet or membrane is preferably a dialysis membrane of molecular weight cut off (MWCO) (as conventionally defined) chosen to allow perfusion of species targeted for sequestration or destruction.

For example, sequestration of the serine protease elastase (molecular weight 25900 Dalton) would require a membrane with MWCO >25900 Dalton.

The MWCO threshold can be varied to suit each application between 1 and 3000000 Dalton. Preferably, the MWCO should be as close as possible to this weight to exclude sequestering interference by larger competitor species.

Both the single-phase system, such as an ultrafiltration unit, and two-phase system, such as a dialysis unit, may be in modular form that is relatively easily demountable from the apparatus of the invention. The system may suitably comprise one or more such modules.

The conduits through which respectively

a) the irrigant and/or wound exudate passes from the wound dressing and
b) the cleansed fluid, still containing materials that are beneficial in promoting wound healing, is returned to the recirculation tube, and
c) (in the case where the means is provided in the form of a two-phase system, such as an dialysis unit) through which the cleansing fluid enters and exits the means

preferably have means for, on module disconnection and withdrawal,

i) switching off the flow and
ii) providing an immediate fluid-tight seal or closure over the ends of the conduits and the cooperating tubes in the rest of the apparatus of the invention so exposed,

to prevent continuing passage of irrigant and/or exudate and cleansed fluid, and cleansing fluid.

The apparatus of the invention for aspirating, irrigating and/or cleansing wounds is provided with means for bleeding the offtake and/or recirculation tubes, such as a regulator, such as a valve or other control device for bleeding fluids from the wound.

The device for moving fluid through the wound and means for fluid cleansing is used to move irrigant to the wound dressing and apply the desired positive or negative pressure on the wound bed.

The desired balance of fluid in recirculation tube will typically be regulated by means of

a) the means for bleeding the offtake and/or recirculation tubes,
b) the means for flow switching between supply and recirculation, and/or
c) the means for moving fluid over the wound bed and through the means for fluid cleansing,

as appropriate.

Thus, e.g. if

a) the apparatus for aspirating, irrigating and/or cleansing wounds is a single-phase system, such as an ultrafiltration unit,
b) the wound is not in a highly exuding state and
c) it is not appropriate or desired to admit fluid into the wound from the fluid reservoir,

there is no or negligible change in the balance of fluid in recirculation.

Once it has been primed throughout, e.g. to the desired positive or negative pressure on the wound bed, the apparatus may be operated as a closed recirculating system.

The means for flow switching between supply and recirculation tubes is set to close the wound to the fluid reservoir via the fluid supply tube, and the means for bleeding the offtake and/or recirculation tubes are also closed.

If

a) the apparatus for aspirating, irrigating and/or cleansing wounds is a single-phase system, such as an ultrafiltration unit,
b) the wound is in a highly exuding state and/or
c) it is appropriate or desired to admit fluid into the wound from the fluid reservoir,

there is a positive change in the balance of fluid in recirculation.

Once it has been primed throughout, e.g. to the desired positive or negative pressure on the wound bed, the apparatus cannot be operated as a closed recirculating system, without the pressure to the wound bed increasing, possibly undesirably.

The means for bleeding the offtake and/or recirculation tubes must be opened to some extent to relieve positive pressure on the wound bed. The bleed-off may be voided to waste, e.g. to a collection bag.
Materials that are beneficial in promoting wound healing may be lost to the site where they can be potentially of most benefit, i.e. the wound bed, when the therapy is applied in this way.

However, the balance of fluid in recirculation may be routinely adjusted to minimise this undesired loss.

The factors that determine the balance of fluid in recirculation in an apparatus with a two-phase system means for fluid cleansing in the form of a dialysis unit, or a biphasic extraction unit have been described hereinbefore in detail hereinbefore in connection with the operation of the apparatus. It is sufficient to note here that at some point after steady state recirculation established through the length of the apparatus flow path, it may be necessary that any bleed valve is opened, if overall the fluid level is increasing by transfer from the dialysate to an undesirable extent.

Other combinations, and the necessary adjustments to maintain the desired balance of fluid in recirculation tube by means of

a) the means for bleeding the offtake and/or recirculation tubes,
b) the means for flow switching between supply and recirculation, and/or
c) the means for moving fluid

will be apparent to the skilled person.

The outlet from the means for bleeding the offtake and/or recirculation tubes may be collected and monitored and used to diagnose the status of the wound and/or its exudate.

The waste reservoir may be of any conventional type, e.g. a tube, bag (such as a bag typically used as an ostomy bag), chamber, pouch or other structure, e.g. of polymer film, which can contain the irrigant fluid that has been bled off. In all embodiments of the apparatus, the type and material of the waste reservoir will be largely determined by its function. To be suitable for use, the material need only be fluid-impermeable once in use, and flexible.

Examples of suitable materials for the fluid reservoir include synthetic polymeric materials, such as polyolefins, such as poly (vinylidene chloride). Suitable materials for the present purpose also include polyethylene, e.g. high-density polyethylene, polypropylene, copolymers thereof, for example with vinyl acetate and mixtures thereof.

In a second aspect of the present invention there is provided a conformable wound dressing, characterised in that it comprises a backing layer with a wound-facing face which is capable of forming a relatively fluid-tight seal or closure over a wound and has
at least one inlet pipe for connection to a fluid supply tube, which passes through and/or under the wound-facing face, and
at least one outlet pipe for connection to a fluid offtake tube, which passes through and/or under the wound-facing face,
the point at which the or each inlet pipe and the or each outlet pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure over the wound.

The dressing is advantageously provided for use in a bacteria-proof pouch.

Examples of suitable forms of such wound dressings are as described by way of example hereinbefore.

It is an object of the present invention

a) to obviate at least some of the disadvantages of known aspiration and/or irrigation therapies, and
b) to provide a system of therapy which

i) can remove materials deleterious to wound healing from wound exudate, whilst retaining materials that are beneficial in promoting wound healing in contact with the wound bed, and/or

ii) which allows fluids containing active amounts of materials that are beneficial in promoting wound healing to pass into and/or through the wound in contact with the wound bed.

Thus, in a third aspect of the present invention there is provided a method of treating wounds to promote wound healing using the apparatus for aspirating, irrigating and/or cleansing wounds of the present invention.

The present invention will now be described by way of example only with reference to the accompanying drawings in which:

Figure 1 is a schematic view of an apparatus for aspirating, irrigating and/or cleansing a wound according to the first aspect of the present invention. It has a single-phase system means for fluid cleansing in the form of an ultrafiltration unit.

Figure 2 is a schematic view of an apparatus for aspirating, irrigating and/or cleansing a wound according to the first aspect of the present invention. It has a two-phase system means for fluid cleansing in the form of a dialysis unit, or a biphasic extraction unit.

In both schematics, any sonode or sonode-transducer is omitted for clarity.

Figures 3 to 8 are cross-sectional views of conformable wound dressings, of the second aspect of the present invention for aspirating and/or irrigating wounds.

Figure 9 is a schematic view of an apparatus for aspirating, irrigating and/or cleansing a wound according to the first aspect of the present invention. It has a single-phase system means for fluid cleansing in the form of an ultrafiltration unit.

Figure 10 is a schematic view of an apparatus for aspirating, irrigating and/or cleansing a wound according to the first aspect of the present invention. It

has a two-phase system means for fluid cleansing in the form of a dialysis unit, or a biphasic extraction unit.

Figure 11 is omitted.

Figure 12 is a view of an apparatus used for the experimental work of Example 3.

Referring to Figure 1, the apparatus (1) for aspirating, irrigating and/or cleansing wounds comprises
a conformable wound dressing (2), having
a backing layer (3) which is capable of forming a relatively fluid-tight seal or closure (4) over a wound (5) and
one inlet pipe (6) for connection to a fluid supply tube (7), which passes through the wound-facing face of the backing layer (3) at (8), and
one outlet pipe (9) for connection to a fluid offtake tube (10), which passes through the wound-facing face at (11),
the points (8), (11) at which the inlet pipe and the outlet pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure over the wound,
means for applying ultrasonic, energy to the wound bed, here a piezoelectric sonode-transducer (111) (not shown), connected to an ultrasonic frequency electrical signal generator run at the appropriate frequencies (112) (not shown)..

The sonode-transducer (111) is mounted distally on the body on the dressing (2) at the fluid inlet pipe (6) where it passes through the wound-facing face of the backing layer (3).

The inlet pipe (6) is connected via means for flow switching between supply and recirculation, here a T- valve (14), by the fluid supply tube (7) to a fluid reservoir (12) and to a fluid recirculation tube (13) having a means for bleeding the tube, here a bleed T-valve (16) to waste, e.g. to a collection bag (not shown),
the outlet pipe (9) being connected to a fluid offtake tube (10), connected in turn to

means for fluid cleansing (17), here in the form of an ultrafiltration unit, connected to the inlet pipe (6) via the fluid recirculation tube (13) and T- valve (14), and

a device for moving fluid through the wound and means for fluid cleansing (17), here a peristaltic pump (18), e.g. preferably a small portable peristaltic pump, acting on the fluid circulation tube (13) with the peripheral rollers on its rotor (not shown) to apply a low negative pressure on the wound.

The ultrafiltration unit (17) is a single-phase system. In this the circulating fluid from the wound and the fluid reservoir passes through a self-contained `system in which materials deleterious to wound healing are removed and the cleansed fluid, still containing materials that are beneficial in promoting wound healing, is returned via the recirculation tube to the wound bed.

(In a variant of this apparatus, there are two inlet pipes (6), which are connected respectively to a fluid supply tube (7) and fluid recirculation tube (13), respectively having a first valve (19) for admitting fluid into the wound from the fluid reservoir (12) and a second valve (20) for admitting fluid into the wound from the recirculation tube. Usually in use of the apparatus, when the first valve (19) is open, the second valve (20) is shut, and vice versa.)
In use of the apparatus (1), the valve (16) is opened to a collection bag (not shown), and the T- valve (14) is turned to admit fluid from the fluid reservoir to the wound dressing through the fluid supply tube (7) and inlet pipe (6).

(In the variant of this apparatus having two inlet pipes (6), which are connected respectively to a fluid supply tube (7) and fluid recirculation tube (13), the first valve (19) for admitting fluid into the wound from the fluid reservoir (12) is opened and the second valve (20) is shut, and vice versa.)

The pump (18) is started to nip the fluid recirculation tube (13) with the peripheral rollers on its rotor (not shown) to apply a low positive pressure on the wound. It is allowed to run until the apparatus is primed throughout the whole length of the apparatus flow path and excess fluid is voided to waste via the bleed T-valve (16) into the collection bag (not shown).

The T-valve (14) is then turned to switch from supply and recirculation, i.e. is set to close the wound to the fluid reservoir (12) but to admit fluid into the

wound from the fluid recirculation tube (13), and the bleed T-valve (16) is simultaneously closed.

(In the variant of this apparatus, where there are two inlet pipes (6), which are connected respectively to a fluid supply tube (7) and fluid recirculation tube (13), the first valve (19) is closed.

A recirculating system is then set up by opening the second valve (20) for admitting fluid into the wound from the recirculation tube (13).)

The circulating fluid from the wound and the fluid reservoir (12) passes through the ultrafiltration unit (17). Materials deleterious to wound healing are removed and the cleansed fluid still containing materials that are beneficial in promoting wound healing is returned via the recirculation tube (13) to the wound bed.

When steady-state recirculation of fluid is achieved, the ultrasonic frequency electrical signal generator (112) (not shown) is started and run at the appropriate frequency to drive the sonode-transducer (111). This may be continued as long as desired.

The recirculation of fluid may be continued as long as desired.

The ultrasonic frequency electrical signal generator (112) (not shown) is then stopped so that it ceases to drive the sonode-transducer (111).

Switching between supply and recirculation is then reversed, by turning the T- valve (14) to admit fluid from the fluid reservoir to the wound dressing through the fluid supply tube (7) and inlet pipe (6).

(In the variant of this apparatus having two inlet pipes (6), which are connected respectively to a fluid supply tube (7) and fluid recirculation tube (13), the first valve (19) for admitting fluid into the wound from the fluid reservoir (12) is opened and the second valve (20) is shut, and vice versa.)

The bleed valve (16) is simultaneously opened, so that fresh fluid flushes the recirculating system.

The running of the pump (18) may be continued until the apparatus is flushed, when it and the fluid recirculation is stopped.

If, e.g. the wound is in a highly exuding state, there is a positive change in the balance of fluid in recirculation.

It may be necessary to bleed fluid from recirculation, by opening the bleed T-valve (16) to bleed fluid from the recirculation tube (13).

Referring to Figure 2, the apparatus (21) is a variant of that of Figure 1, with identical, and identically numbered, components, except for the means for fluid cleansing, which is in the form of a two-phase system, here a dialysis unit (23).

In this, there is one system through which the circulating fluid from the wound and the fluid reservoir passes and from which deleterious materials are removed by selectively permeable contact with a second system, through which passes a cleansing fluid.

The dialysis unit (23) thus has an internal polymer film, sheet or membrane (24), selectively permeable to materials deleterious to wound healing, which divides it into

a) a first chamber (25), through which passes a cleansing fluid across one surface of the polymer film, sheet or membrane, and
b) a second chamber (26), through which passes the circulating fluid from the wound and the fluid reservoir (12), and from which deleterious materials are removed

The dialysis unit (23) thus has a dialysate inlet pipe (28) connecting to a dialysate supply tube (29) which passes to a peristaltic pump (38), e.g. preferably a small portable peristaltic pump, acting on the dialysate supply tube (29) with the peripheral rollers on its rotor (not shown) to supply cleansing fluid across the surface of the polymer film, sheet or membrane (24) in the first chamber (25) from a dialysate reservoir (not shown) via a valve (34).

The dialysis unit (23) also has a dialysate outlet pipe (30) connecting to a dialysate outlet tube (31) which passes to waste via a second bleed T-valve (36) into, e.g. a collection bag (not shown).

Operation of this apparatus is similar to that of Figure 1, except for the dialysis unit (23), in that at some point after the irrigation system is primed and steady state recirculation established through the length of the apparatus flow path, the valve (34) and second bleed valve (36) are opened.

The pump (38) is started to nip fluid dialysate tube (29) with the peripheral rollers on its rotor (not shown) to pump cleansing fluid to the first chamber from a dialysate reservoir (not shown) and out to waste via the bleed valve (36) into the collection bag (not shown).

When steady-state recirculation of fluid is achieved, the ultrasonic frequency electrical signal generator (112) (not shown) is started and run at the appropriate frequency to drive the sonode-transducer (111). This may be continued as long as desired.

The dialysis unit (23) is a module (or scrubbing cartridge) with a substrate that changes colour to indicate the presence of detrimental factors in the cleansed fluid, and that the scrubbing cartridge is exhausted and should be renewed.

In a variant of the apparatus shown in Figure 2, the dialysis unit has a first chamber (25), but one in which the cleansing fluid is static.

The device for moving fluid through the wound and means for fluid cleansing (17) in Figure 2, a peristaltic pump (18), may optionally act on the fluid supply tube (7) as well as the fluid recirculation tube (13).

Referring to Figure 3, a form of dressings for deeper wounds is shown. This comprises a circular backing layer (342) and a chamber (363) in the form of a deeply indented disc much like a multiple Maltese cross.

This is defined by an upper impervious membrane (361) and a lower porous film (362) with apertures (364) that deliver the irrigant fluid directly from the wound bed over an extended area.

The chamber (363) is able to conform well to the wound bed by the arms closing in and possibly overlapping in insertion into the wound.

The space above the chamber (363) is filled with an elastically resilient foam or loose gauze.

A piezoelectric sonode-transducer (111) is mounted on the upper face of the backing layer (342), and is connected to an ultrasonic frequency electrical signal generator run at the appropriate frequencies (112) (shown schematically) by electrical leads (113).

It is a sheet or membrane of a piezoelectric transducing polyolefin, such as polyvinylidene fluoride and copolymers thereof, and is adhered with a curable adhesive to the dressing.

An inlet pipe (346) and outlet pipe (347) are mounted centrally in a boss (351) on the sonode-transducer (111) on the backing layer (342), and pass through both.

The inlet pipe (346) communicates with the interior of the chamber (348). The outlet pipe (347) extends radially to just below the backing layer (342) to communicate with the interior of the pouch (363).

Referring to Figure 4, this form of the dressing is provided with a wound filler (348) under a circular backing layer (342).

The filler (348) comprises a generally downwardly domed toroidal conformable hollow body, defined by a membrane (349) which is filled with a fluid, here air or nitrogen, that urges it to the wound shape. The filler (348) is permanently attached to the backing layer via a boss (351), which is e.g. heat-sealed to the backing layer (342).

An annular layer of foam (364) formed of a suitable material, e.g. a resilient thermoplastic, surrounds the boss (351). Preferred foam materials include reticulated filtration polyurethane foams with small apertures or pores.

A piezoelectric sonode-transducer (111) is mounted on the underside of the boss (351), and is connected to an ultrasonic frequency electrical signal generator run at the appropriate frequencies (112) (shown schematically) by electrical leads (113) running through the boss (351).

It is a sheet or membrane of a piezoelectric transducing polyolefin, such as polyvinylidene fluoride and copolymers thereof, and is adhered by heat lamination to the dressing.

An inflation inlet pipe (350), inlet pipe (346) and outlet pipe (347) are mounted centrally in the boss (351) in the backing layer (342). The inflation inlet pipe (350) communicates with the interior of the hollow body (348), to permit inflation of the body (348). The inlet pipe (346) extends in a pipe (352) through boss (351).

The outlet pipe (347) extends radially immediately under the backing layer (342), and collects fluid flowing radially through the foam layer (364) from the wound periphery when the dressing is in use.

Referring to Figure 5, this form of the dressing is a variant of that of Figure 4, with identical, and identically numbered, components, except for the following:

A downwardly domed membrane (361) with apertures (362) is permanently attached at its periphery by heat-sealing to, and lies underneath, the filler (348), to form an inlet manifold (353). The pipe (352) communicates with the interior of the inlet manifold (353), but not through the piezoelectric sonode-transducer (111).

This is still mounted on the underside of the boss (351), but spaced from it by struts (372) defining peripheral channels or conduits (363) that communicate between the pipe (352) and the inlet manifold (353).

Referring to Figure 6, the dressing is also provided with a wound filler (348) under a circular backing layer (342).
This comprises a generally oblately spheroidal conformable hollow body, defined by a membrane (349) which is filled with a fluid, here air or nitrogen, that urges it to the wound shape. The filler (348) is permanently attached to the backing layer via a boss (351), which is e.g. heat-sealed to the backing layer (342).

An inflation inlet pipe (350), inlet pipe (346) and outlet pipe (347) are mounted centrally in the boss (351) in the backing layer (342) above the hollow body (348). The inflation inlet pipe (350) communicates with the interior of the hollow body (348), to permit inflation of the body (348). The inlet pipe (346) extends in a pipe (352) effectively through the hollow body (348). The outlet pipe (347) extends radially immediately under the backing layer (342).

The lower end of the inlet pipe (346) is splayed into a funnel (356), in part of the wall of which is a recess (357). A sonode-transducer, such as an Exogen ™ device (111) is a tight push fit in the recess.

It is connected to an ultrasonic frequency electrical signal generator run at the appropriate frequencies (112) (shown schematically) by electrical leads (113) running through the boss (351) and the hollow body (348).

Referring to Figure 7, this form of the dressing is a variant of that of Figure 6, with identical, and identically numbered, components, except that the sonode-transducer, whilst mounted in the same overall position is not in a recess, but within the hollow body (348).

This form of the dressing is a more suitable layout for deeper wounds

Referring to Figure 8a, another form for deeper wounds is shown. This comprises a circular, or more usually square or rectangular backing layer (342) and a chamber (363) in the form of a deeply indented disc much like a multiple Maltese cross or a stylised rose.

This is defined by an upper impervious membrane (361) and a lower porous film (362) with apertures (364) that deliver the irrigant fluid directly to the wound bed over an extended area, and thus effectively forms an inlet manifold. Three configurations of the chamber (363) are shown in Figure 8b, all of which are able to conform well to the wound bed by the arms closing in and possibly overlapping in insertion into the wound.

The space above the chamber (363) is filled with a wound filler (348) under the backing layer (342). This comprises an oblately spheroidal conformable hollow body, defined by a membrane (349) that is filled with a fluid, here air or nitrogen, that urges it to the wound shape.

A piezoelectric sonode-transducer (111) is mounted on the upper face of the backing layer (342), and is connected to an ultrasonic frequency electrical signal generator run at the appropriate frequencies (112) (shown schematically) by electrical leads (113).

It is a sheet or membrane of a piezoelectric transducing polyolefin, such as polyvinylidene fluoride and copolymers thereof, and is adhered with a curable adhesive to the dressing.

A moulded hat-shaped boss (351) is mounted centrally on the upper impervious membrane (361) of the chamber (363). It has three internal channels, conduits or passages through it (not shown), each with entry and exit apertures. The filler (348) is attached to the membrane (361) of the chamber (363) by adhesive, heat welding or a mechanical fixator, such as a cooperating pin and socket.

An inflation inlet pipe (350), inlet pipe (346) and outlet pipe (347) pass under the edge of the proximal face of the backing layer (342) of the dressing, and extend radially immediately under the filler (348) and over the membrane

(361) of the chamber (363) to each mate with an entry aperture in the boss (351).

An exit to the internal channel, conduit or passage through it that receives the inflation inlet pipe (350) communicates with the interior of the hollow filler (348), to permit inflation.
An exit to the internal channel, conduit or passage that receives the inlet pipe (346) communicates with the interior of the chamber (363) to deliver the irrigant fluid via the chamber (363) to the wound bed over an extended area.

Similarly, an exit to the internal channel, conduit or passage that receives the outlet pipe (347) communicates with the space above the chamber (363) and under the wound filler (348), and collects flow of irrigant and/or wound exudate radially from the wound periphery.

Referring to Figure 9, the apparatus (1) for aspirating, irrigating and/or cleansing wounds is a variant of the apparatus (1) of Figure 1.

It has bypass (711) around the pump (18), as a protection of the pump against any blockage in the system.

It is activated automatically by appropriate means, e.g. it is normally blocked by a bursting disc (not shown), or a pressure-activated motorised valve.

An alternative to the by-pass (711) is a pressure sensor in the system that will detect excessive load or pressure, and shut down the pump.

Referring to Figure 10, the apparatus (1) for aspirating, irrigating and/or cleansing wounds is a variant of the apparatus (21) of Figure 2.

The latter is a two-phase system with a dialysis unit (21), but is one in which dialytic fluid passes only once across the surface of the dialytic membrane (24) in the first chamber (25) from a dialysate reservoir (not shown) to waste via a second bleed T-valve (816) into, e.g. a collection bag (not shown).

This variant has a dialysate recirculation tube (811) running between a first T-valve (816) on the inlet side of the dialysate pump (38) and a second T-valve (817) to permit the pump (38) to recirculate the dialysate once the circuit is primed in multiple passes through the dialysis unit (23).

The operation of the system will be apparent to the skilled person.
Referring to Figure 11, the apparatus (1) for aspirating, irrigating and/or cleansing wounds is a major variant of the apparatus shown in Figure 1.

The device for moving fluid through the wound and means for fluid cleansing (17) in Figure 1 is a peristaltic pump (18), e.g. preferably a small portable peristaltic pump, acting on the fluid circulation tube (13) downstream of the dressing (2) to apply a low negative pressure on the wound.

Peter,
I have a problem with Fig.11. It would work if (918) was a peristaltic pump moving fluid from the vacuum waste collection chamber into the recirculation loop, BUT (926) would do this job alone. To put chamber (911) under vacuum would require a vacuum pump moving air out of (911) to create a vacuum, as in our current development product You're right. The main problem is that this type of assembly is really only appropriate for aspirate irrigate, and as originally described had no recirculation loop; we had to fudge it in to Exu. It adds nothing, and will take too much to remedy it. I've deleted it, and will delete from the drawings.

The use of the apparatus of the present invention will now be described by way of example only in the following Examples:

<u>Example 1. The combination of the removal by dialysis of materials deleterious to wound healing (H_2O_2) by an enzyme (catalase) retained in a static second phase and ultrasound waves.</u>

An apparatus of the present invention was constructed essentially as in the variant of the apparatus of Figure 2, described above, i.e. one in which the means for fluid cleansing is a two-phase system dialysis unit, but with a static dialysate phase.

In such an apparatus, an irrigant and/or wound exudate first phase from the wound recirculates through a first circuit. It passes over a selectively permeable dialysis membrane that separates it from a static second fluid (dialysate) phase.

Hydrogen peroxide is produced in conditions of oxidative stress following reduced blood flow and or the inflammatory response to bacterial contamination of wounds. It may be removed by the appropriate antagonists and/or degraders, which include enzymic or other inhibitors, such as peroxide degraders, e.g. catalase.

The first circuit comprised a surrogate wound chamber (Minucells perfusion chamber) in which normal diploid human fibroblasts were cultured on 13 mm diameter (Thermanox polymer) cover slips retained in a two part support (Minucells Minusheets). Tissues present in the healing wound that must survive and proliferate were represented by the cells within the chamber.

After an overnight serum starvation, nutrient medium (DMEM with 5% FCS with 1% Buffer All) to simulate wound exudate was pumped from a reservoir into the lower aspect of the chamber where it bathed the fibroblasts and was removed from the upper aspect of the chamber and returned to the reservoir.

The first circuit also includes, upstream of the wound chamber, a static second phase dialysis unit, comprising a length of dialysis tubing (Pierce Snake skin 68100 CG 49358B, 10KD cut off) placed within the first circuit reservoir in which a static second phase second cleansing circuit containing nutrient media with between 5,000 and 50,000 units (μ moles H_2O_2 degraded per min at pH7, 25°C) per ml of catalase (in a circuit with a reservoir and total volume of between 5.0 ml and 75 ml) at a flow rate of between 0.5 ml min^{-1} and 5.0 ml min^{-1}.

The pump was a peristaltic pump acting on silicone (or equivalent) elastic tubing. The internal diameter of the tubing was 1.0 mm. A total volume for the first circuit including the chamber and the reservoir at a number of values

between 25 and 75 ml was used. The flow rates used were at a number of values between 0.5 ml min^{-1} and 5.0 ml min^{-1}.

An experiment was conducted that simulated conditions not uncommon for healing wounds whereby the nutrient medium containing a material deleterious to wound healing, namely hydrogen peroxide, was circulated over the cells.

An ultrasound signal was generated for 20 minutes with a high power driver, set at 100mW/cm^2, driving standard transducers) was applied to the base of the Minucell chambers whilst media was flowing in the first circuit.

A control experiment is also conducted where ultrasound waves were omitted.

Results and Conclusions

The following results were obtained for a first phase circuit comprising a wound chamber as above containing nutrient media (75 ml) with H_2O_2 (10μM).

This was pumped at a flow rate of 1.0 ml min^{-1} in contact with a static second phase (15 ml) containing catalase (7,600 units ml^{-1}), where the wound chamber and media were held at 37°C for 24 hours.

Conditions	Mean level of cell activity* after 24 hours incubation.
Nutrient media only	0.28
Media with H_2O_2 only	0.00
H_2O_2 + catalase 2nd phase dialysis unit	0.29
H_2O_2 + catalase 2nd phase dialysis unit + ultrasound	0.34

*Cell activity measured with a WST (Tetrazolium based mitochondrial dehdrogenase activity assay).

In the controls where either

a) the passage of the nutrient flow across the cleansing membrane dialysis unit or

b) the ultrasound waves were omitted.

and the concentration of H_2O_2 lies between 5 and 20 mM survival, growth of the fibroblasts is inhibited.

However, when the nutrient medium flow in the first circuit is

a) passed over the membrane dialysis unit in which a second cleansing circuit containing catalase (at the concentrations and flow rates noted above) is present, and

ultrasound waves are delivered to the base of the Minucell chamber the fibroblasts survive and proliferate to a greater extent than in the control circuits..

The combination of the wound cleansing dialysis unit that removes and degrades H_2O_2 and the addition of the ultrasound waves enhances the cell response necessary for wound healing.

Example 2: The combination of the removal by dialysis of materials deleterious to wound healing (H_2O_2) by an enzyme (catalase) retained in a moving second phase and ultrasound.

An apparatus of the present invention is constructed essentially as in Figure 2, i.e. one in which the means for fluid cleansing is a two-phase system dialysis unit. In such an apparatus, an irrigant and/or wound exudate first phase from the wound recirculates through a first circuit and passes in through the dialysis unit in contact across a selectively permeable dialysis membrane with a second fluid (dialysate) phase. The dialysis unit is operated with the two phases flowing counter-current to each other.

Hydrogen peroxide is produced in conditions of oxidative stress following reduced blood flow and or the inflammatory response to bacterial contamination of wounds. It may be removed by the appropriate antagonists and/or degraders, which include enzymic or other inhibitors, such as peroxide degraders, e.g. catalase.

The first circuit comprises a surrogate wound chamber (Minucells perfusion chamber) in which normal diploid human fibroblasts are cultured on 13 mm

diameter (Thermanox polymer) cover slips retained in a two-part support (Minucells Minusheets). Tissues present in the healing wound that must survive and proliferate are represented by the cells within the chamber. After overnight serum starvation nutrient medium (DMEM with 5%FCS with 1% Buffer All) to simulate wound exudate is pumped from a reservoir into the lower aspect of the chamber where it bathed the fibroblasts and is removed from the upper aspect of the chamber and returned to the reservoir.

The first circuit also comprises

a) Upstream of the wound chamber, a luer-fitting hollow fibre tangential membrane dialysis unit (Spectrum® MicroKros® X14S-100-04N, 8 cm^2 surface area, 400KD Mol. Wt. cut off,) through which a second cleansing circuit containing nutrient media with between 5,000 and 50,000 units (μ moles H_2O_2 degraded per min at pH7, 25°C) per ml of catalase (in a circuit with a reservoir and total volume of between 5.0 mL and 20 mL) at a flow rate of between 0.5 ml min^{-1} and 5.0 ml min^{-1} could be passed in a counter current direction, and

b) ultrasound waves are delivered to the base of the Minucell chamber.

The pumps for the two circuits are peristaltic pumps acting on silicone tubing or equivalent. The internal diameter of the tubing is 1.0 mm. A total volume for the first circuit including the chamber and the reservoir at a number of values between 25 and 75 ml is used. The flow rates used are at a number of values between 0.5 ml min^{-1} and 5.0 ml min^{-1}.

Experiments are conducted that simulated conditions not uncommon for non-healing wounds whereby the nutrient medium containing a material deleterious to wound healing, namely hydrogen peroxide, is circulated over the cells.

First and second control apparatus are also constructed essentially as in Figure 2, but where either

a) the cleansing membrane dialysis unit is omitted, so that the nutrient flow passes directly from the reservoir, or

b) the 20-minutes ultrasound signal is omitted.

In controls where either

a) the passage of the nutrient flow through the cleansing membrane dialysis unit or

b) the 20 minute ultrasound signal is omitted, and

c) the concentration of H_2O_2 lies between 5 and 20 mM,

fibroblast activity and proliferation is inhibited or not stimulated.

However, when the nutrient medium flow in the first circuit is

a) connected into the ends of the membrane dialysis unit through which a second cleansing circuit containing catalase (at the concentrations and flow rates noted above) is passing in a counter current direction, and

b) an ultrasound signal is generated for 20 minutes with a high power driver, set at 100mW/cm^2, driving standard transducers) is applied to the base of the minucell chambers whilst media is flowing in the first circuit.

the fibroblasts survive and proliferate to a greater extent during a 24 hour period than the control circuits.

Example 3 – Demonstration of the presence of ultrasound at the base of a wound whilst the wound is subjected to simultaneous irrigation and aspiration at reduced pressure and ultrasound delivered through the backing layer of a wound dressing of the present invention.

The experimental set-up was as shown in Figure 12 in which an ultrasound detector assembly (801) with a detector (802) and a signal cable (811) was centrally placed, detector (802) uppermost, at the bottom of a Perspex wound model cavity (803) (130mm diameter top opening; 30mm depth), and fixed in a horizontal position using a block of adhesive putty.

A dressing inlet manifold (804) comprises an inlet chamber (805) defined by an upper impermeable layer (806) and a lower permeable layer (807) and an irrigant delivery tube (808) passing into an irrigant inlet (809).

The manifold (804) was placed on top of the detector assembly (801), and a wound filler (810) in the form of a block of reticulated polyurethane foam was placed on top of the manifold (804). The irrigant delivery tube (808) to the

manifold (804) and the cable (811) from the ultrasonic detector (802) were fed under the filler (810), and then through pre-formed channels in a polyurethane side port (812). Care was taken to keep the cable (811) and tube (808) from passing over the ultrasound detector (802).

The end of the irrigant delivery tube (808) furthest from the manifold (804) was connected to a peristaltic irrigant pump (817) (Ismatech IPC pump), in turn connected to an irrigant reservoir (818) (1000ml Schott Duran).

The end of the cable (811) furthest from the detector (802) was connected to an oscilloscope (819) (Tektronix TDS 3014).

An aspiration tube (813) also passes through the side port (812), but only extends into the wound cavity (803) a short distance, and was laid on top of the filler (810). The end of the aspiration tube (813) furthest from the cavity (3) was connected to a vacuum vessel (820) (150ml polystyrene vacuum jar (Nalgene)) with pressure monitor (Living Systems Instrumentation) and pressure sensor (823).
The monitor was in turn connected via a pressure control valve (821) to a diaphragm vacuum pump (822) (Schwarz diaphragm vacuum pump and associated DC power supply (12V))

The side port (812) was bonded to the top of the wound model with an acrylic pressure sensitive adhesive.

An adhesive-coated Opsite film backing layer (814) was placed over the wound model to cover the cavity (803) and the side port (812). In order to achieve an air- and liquid-tight seal, additional pressure sensitive adhesive was placed around the tubes (808), (813) and cable (811) at the point where they left the side port (812).

An annular ultrasound transducer holder (815) was bonded to the upper surface of the Opsite backing layer (814) using unsupported pressure sensitive adhesive. A small blob of ultrasound coupling gel was placed on the film area encircled by the holder (815).

A cylindrical ultrasound transducer unit (816) (28mm diameter; 11mm depth) from a low intensity ultrasound source (Exogen 2000+ fracture healing system (Smith & Nephew) was connected to the ultrasound signal generator (824) from such a system. The unit (816) provides low intensity ultrasound comparable to the diagnostic ultrasound intensities used in sonogram (foetal monitoring) procedures, and only 1% to 5% of the intensity used in conventional therapeutic ultrasound.

The unit (816) is dimensioned to mate with the holder (815) in a sliding push fit, and was pushed into the holder (815), at which point it was fully in contact with the coupling gel.

The peristaltic irrigant pump (817) was started to pump irrigant into the wound cavity (803). Once the cavity (803) was full, the irrigation pump was stopped, and the diaphragm pump (822) was started and negative pressure was established in the wound cavity (803) and held at 81.9mmHg below atmospheric pressure as monitored at the vacuum vessel (820).)

Once the pressure had stabilised, the irrigation pump was restarted (flow rate ~95ml/hr) and simultaneous irrigation and aspiration was initiated.

At this point the ultrasonic signal generator (824) was set up and turned on such that the unit (816) provides low intensity ultrasound at a frequency of 1.5 ± 5% MHz, with a modulating signal burst width of 200 ± 10% microseconds at a repetition rate of 1.0 ± 10% KHz (800 microsecond intervals) at a temporal average power of 117 ± 30% mW,

Results

A signal with the same signal burst width and repetition rate as that produced by the ultrasound generator was detected at the model wound bed.
The detected signal strength gradually increased as the top film was drawn down into the model wound by the applied negative pressure.

Conclusion

Ultrasound, delivered through the backing layer of a dressing of the present invention reaches the wound bed of a wound model whilst the wound cavity

was subjected to simultaneous irrigation with water and aspiration at reduced pressure.

Claims

1. An apparatus for irrigating, flow stressing and/or cleansing wounds, characterised in that it comprises

a) a fluid flow path, comprising

i) a conformable wound dressing, having

a backing layer which is capable of forming a relatively fluid-tight seal or closure over a wound and

at least one inlet pipe for connection to a fluid supply tube, which passes through and/or under the wound-facing face, and

and at least one outlet pipe for connection to a fluid offtake tube, which passes through and/or under the wound-facing face,

the point at which the or each inlet pipe and the or each outlet pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure over the wound,

at least one inlet pipe being connected to a fluid recirculation tube, and at least one outlet pipe being connected to a fluid offtake tube: and

ii) a means for fluid cleansing having at least one inlet port connected to a fluid offtake tube and at least one outlet port connected to a fluid recirculation tube;

b) a fluid reservoir connected by a fluid supply tube to an integer of the flow path (optionally or as necessary via means for flow switching between supply and recirculation);

c) a device for moving fluid through the wound dressing and means for fluid cleansing, and optionally or as necessary the fluid supply tube; and

d) optionally means for bleeding the flowpath,

characterised in that it comprises

e) means for applying high frequency vibrational energy to the wound bed;

such that fluid may be supplied to fill the flowpath from the fluid reservoir via the fluid supply tube (optionally or as necessary via the means for flow switching) and recirculated by the device through the flow path.

2. An apparatus according to claim 1, characterised in that the means for applying high frequency vibrational energy to the wound bed is means for applying ultrasonic energy to the wound bed.

3. An apparatus according to claim 1, characterised in that the means for applying high frequency vibrational energy to the wound bed comprises a high frequency vibrational sonode or a component of the apparatus flow path connected to a sonode.

4. An apparatus according to claim 1, characterised in that the means for applying high frequency vibrational energy to the wound bed is
a) mounted distally of the body on, in or inside of the dressing; or
b) mounted in, on, at or near one or more of the fluid inlet pipes and outlet pipes that pass through and/or under the wound-facing face of the backing layer.

5. An apparatus according to claim 1, characterised in that it comprises a means for fluid cleansing that is a single-phase system, in which the circulating fluid from the wound passes through the means for fluid cleansing and materials deleterious to wound healing are removed, without the circulating fluid coming into direct or indirect contact with another fluid in the means for fluid cleansing.

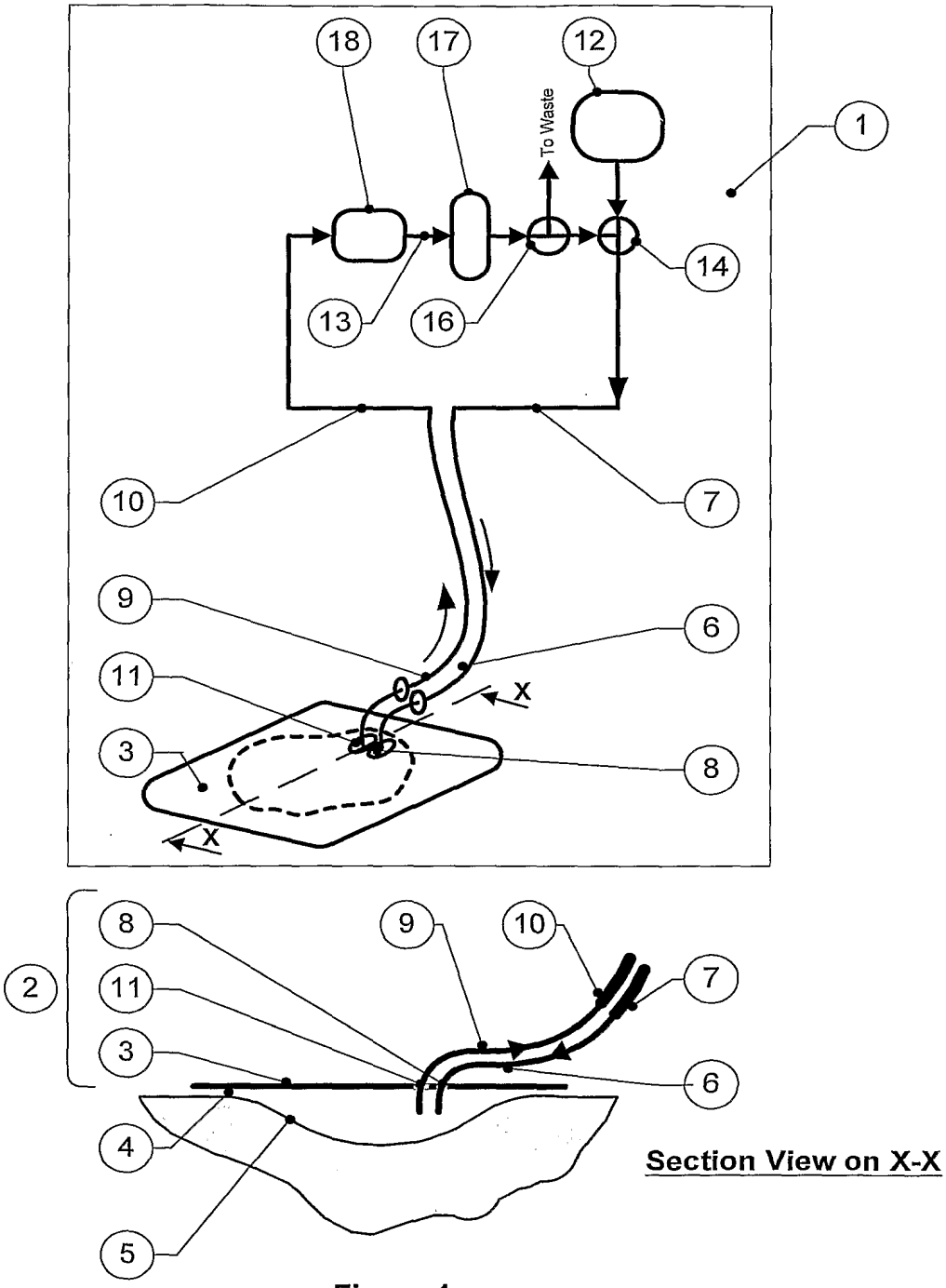
6. An apparatus according to claim 1, characterised in that it comprises a means for fluid cleansing that is a two-phase system, in which the circulating fluid from the wound passes through the means for fluid cleansing and materials deleterious to wound healing are removed, by the circulating fluid coming into direct or indirect contact with another fluid in the means for fluid cleansing.

7. An apparatus according to claim 3, characterised in that in the means for fluid cleansing, the circulating fluid from the wound and the other fluid in the means for fluid cleansing are separated by an integer which is selectively permeable to materials deleterious to wound healing.

8. An apparatus according to claim 3, characterised in that in the means for fluid cleansing, the circulating fluid from the wound and the other fluid in the means for fluid cleansing are separated by an integer which is not selectively permeable to materials deleterious to wound healing, and the other fluid comprises and/or is in contact with a material that removes materials deleterious to wound healing.

9. A conformable wound dressing for use in an apparatus according to claim 1 that comprises
a backing layer with a wound-facing face which is capable of forming a relatively fluid-tight seal or closure over a wound and has
at least one inlet pipe for connection to a fluid supply tube, which passes through and/or under the wound-facing face, and
at least one outlet pipe for connection to a fluid offtake tube, which passes through and/or under the wound-facing face,
the point at which the or each inlet pipe and the or each outlet pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure over the wound,
characterised in that it comprises means for applying high frequency vibrational energy to the wound bed.

10. A method of treating wounds to promote wound healing using the apparatus according to claim 1.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Section View on X-X

Figure 1

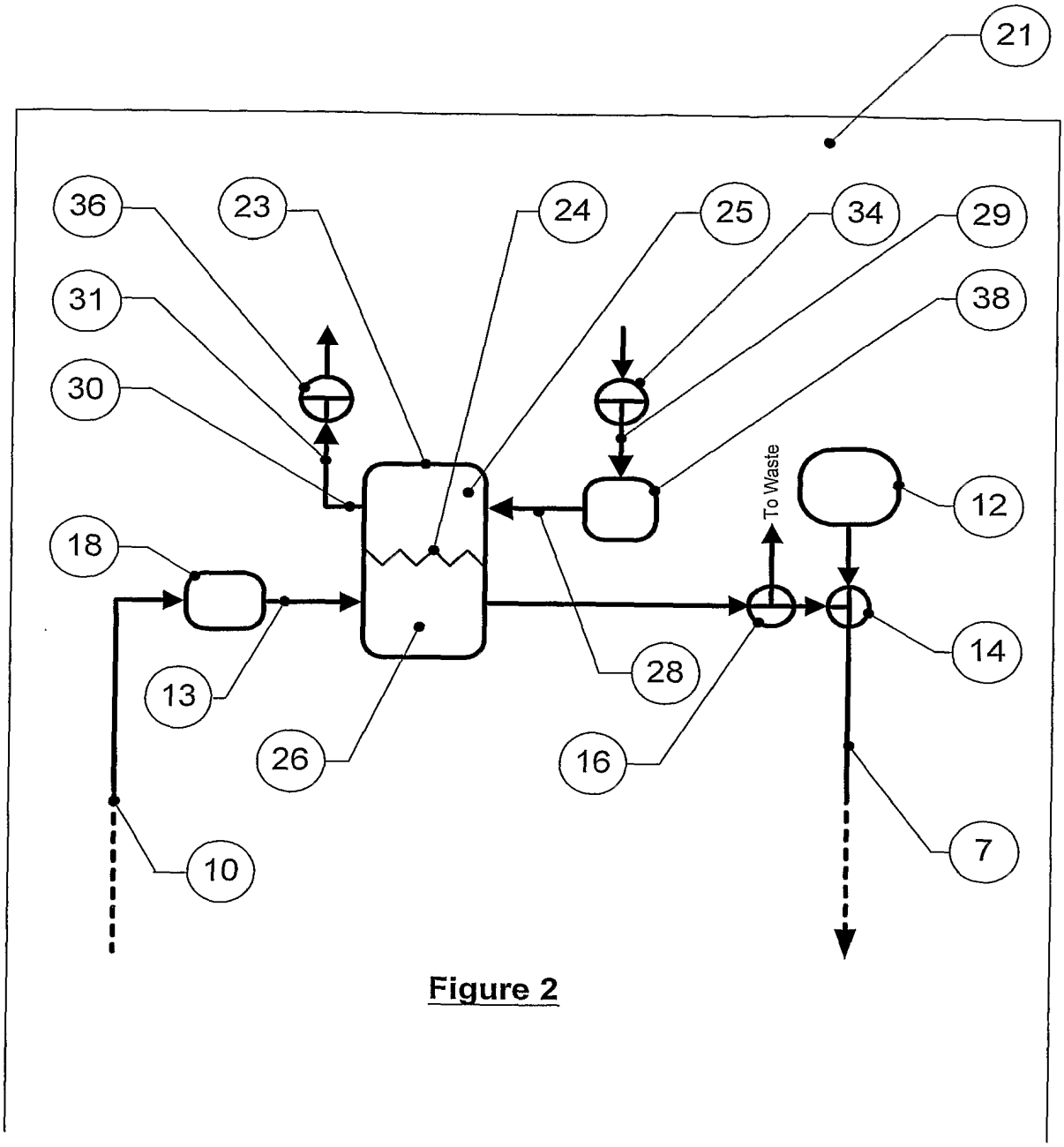


Figure 2

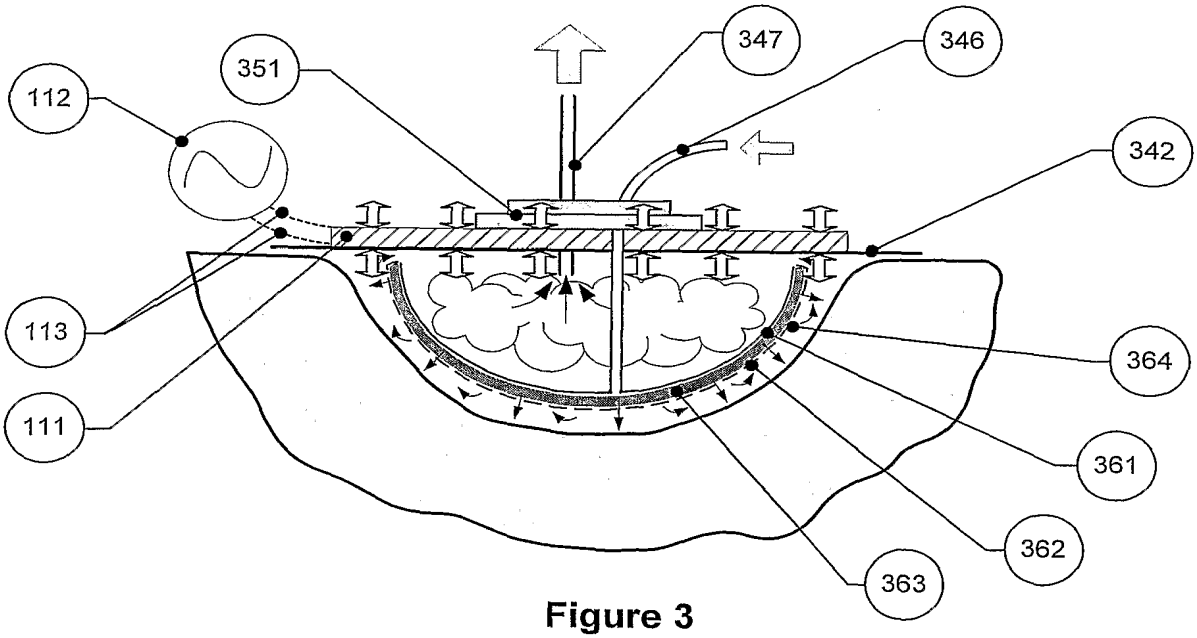


Figure 3

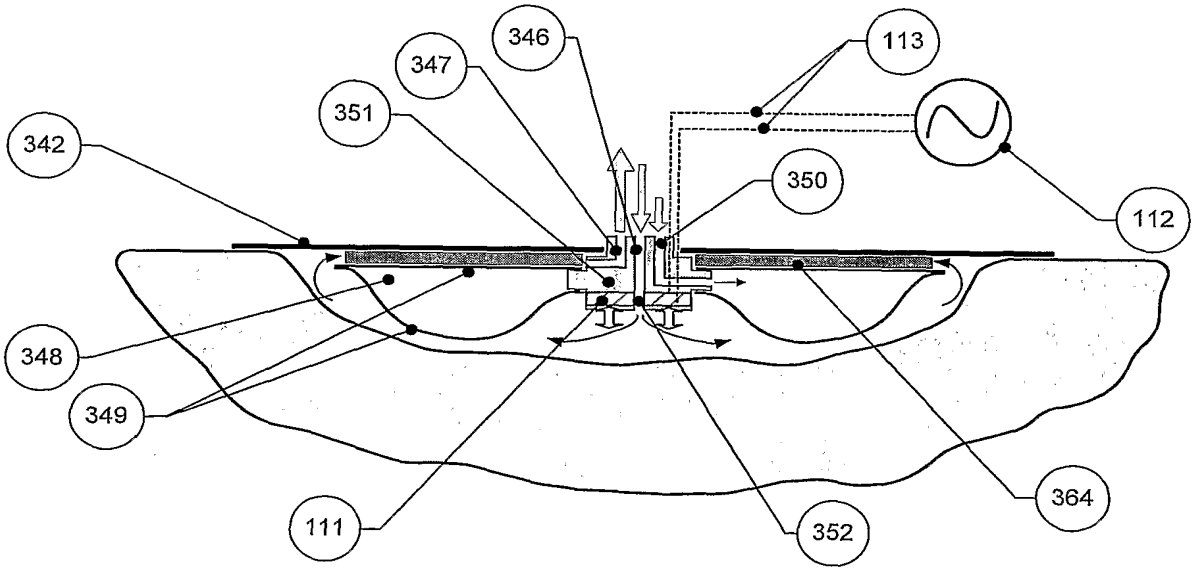


Figure 4

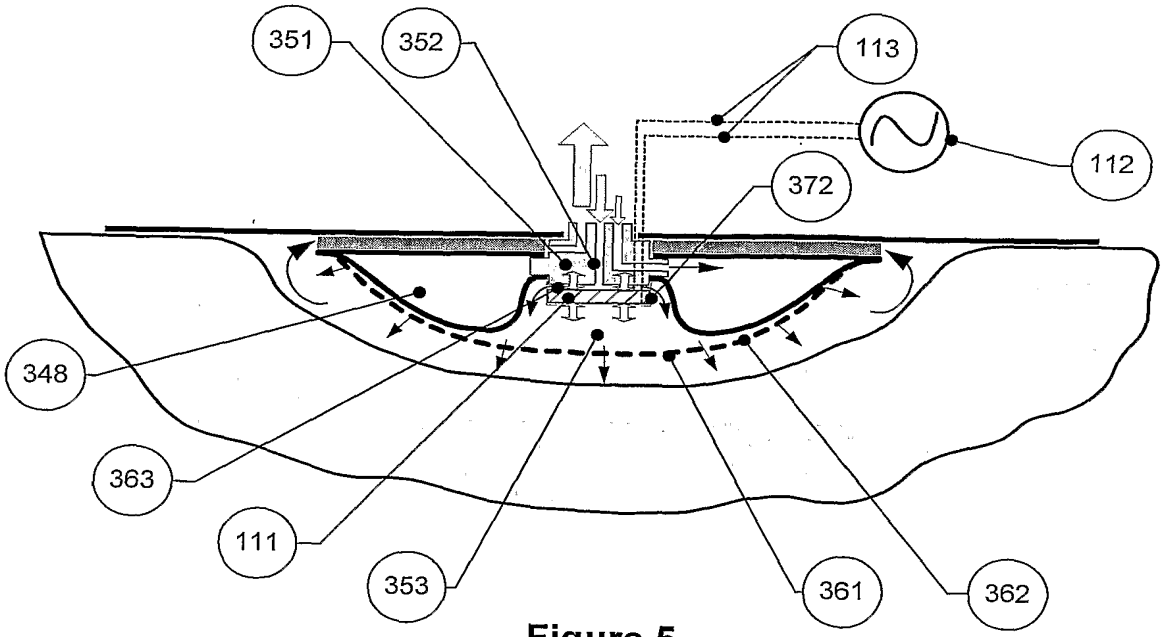


Figure 5

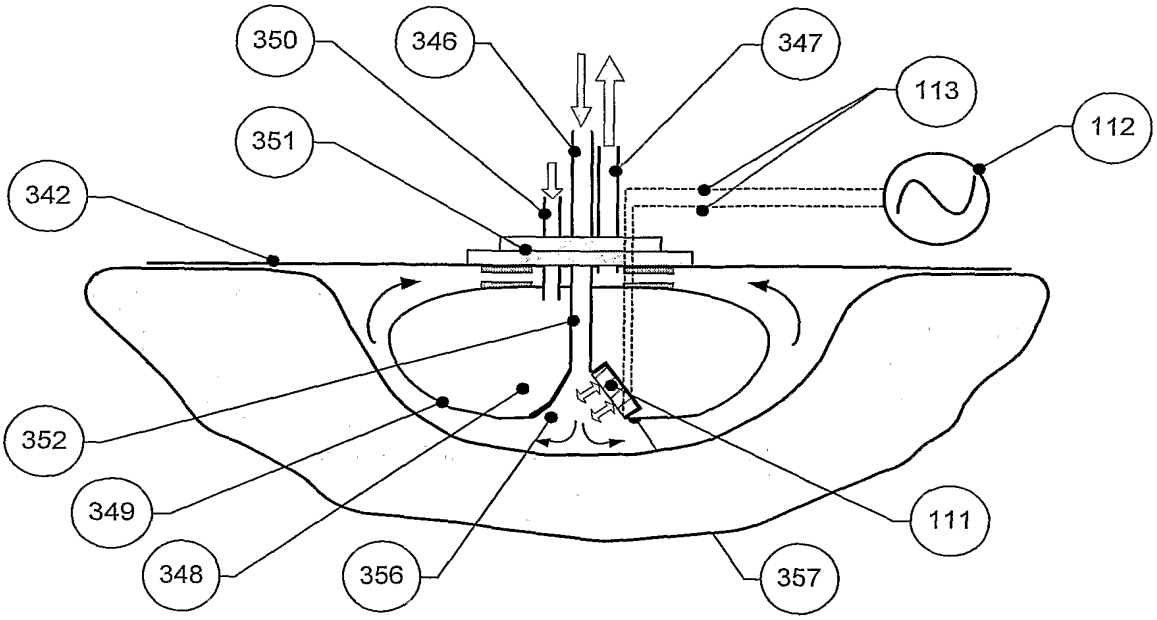


Figure 6

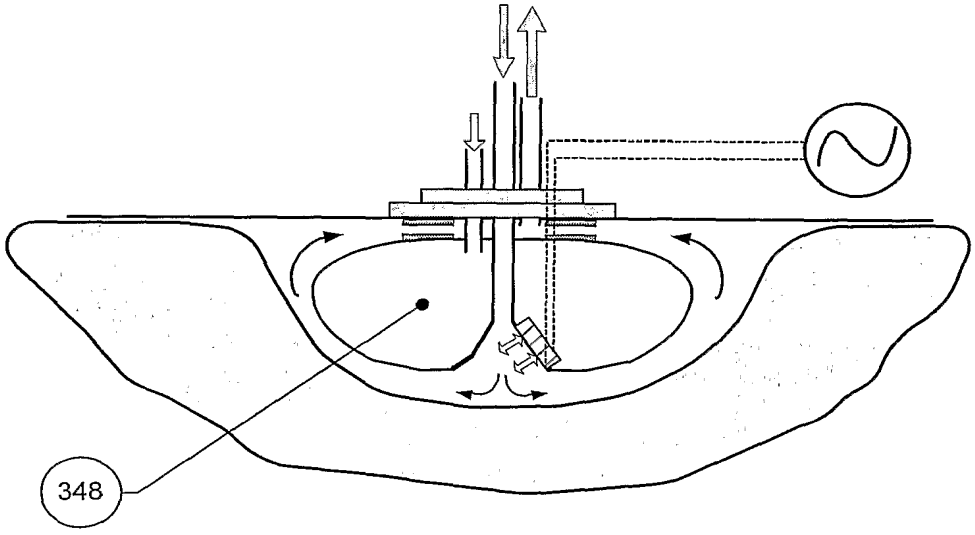


Figure 7

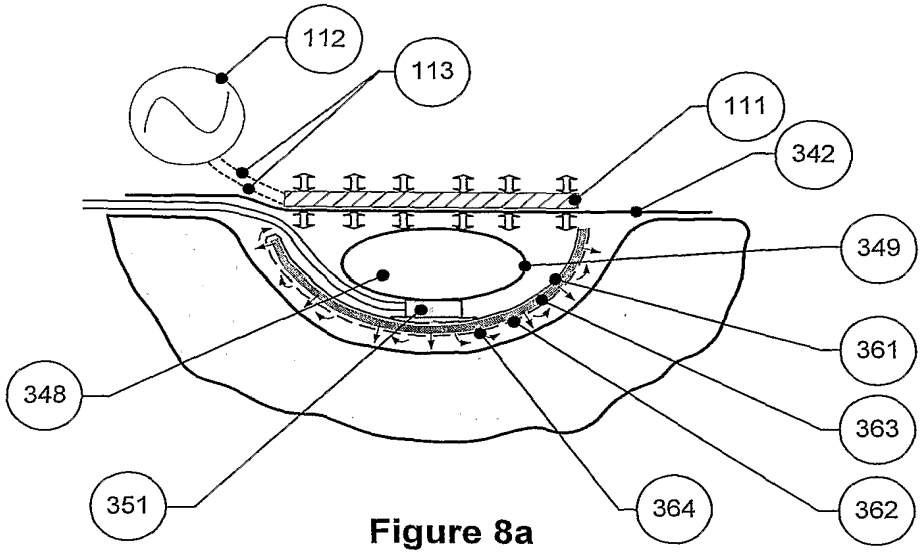


Figure 8a

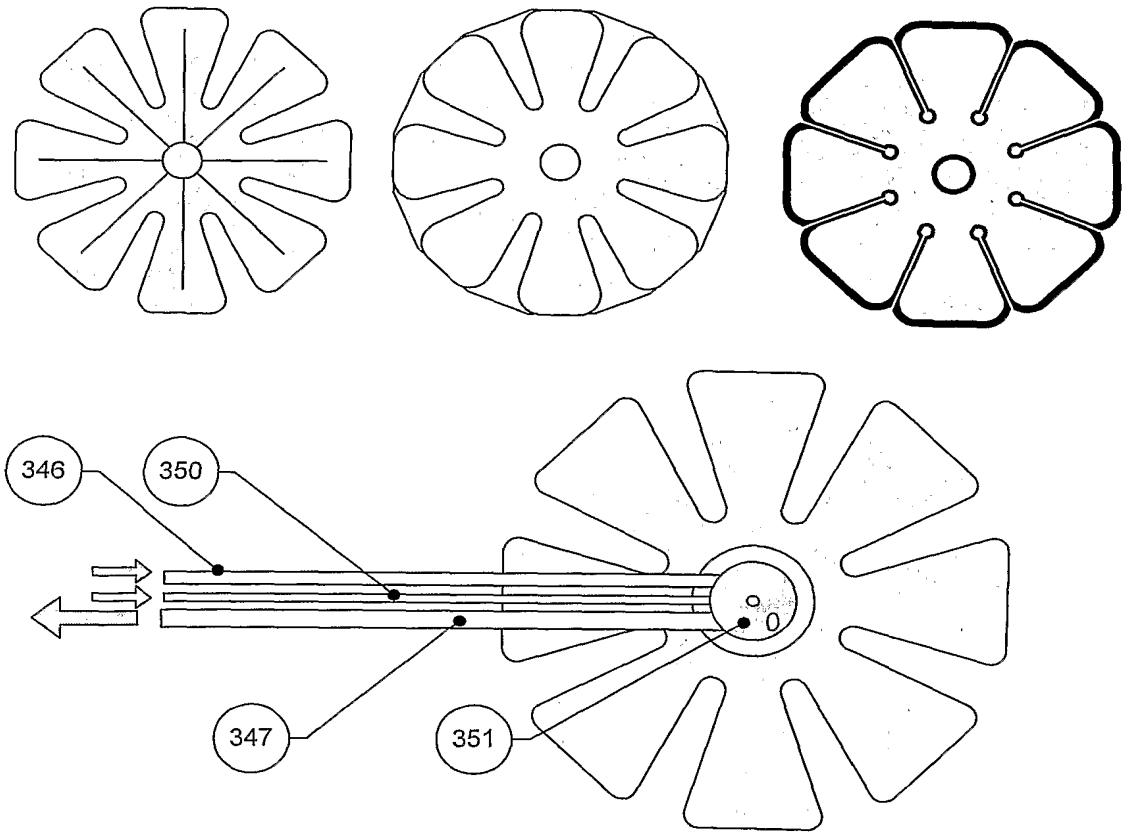
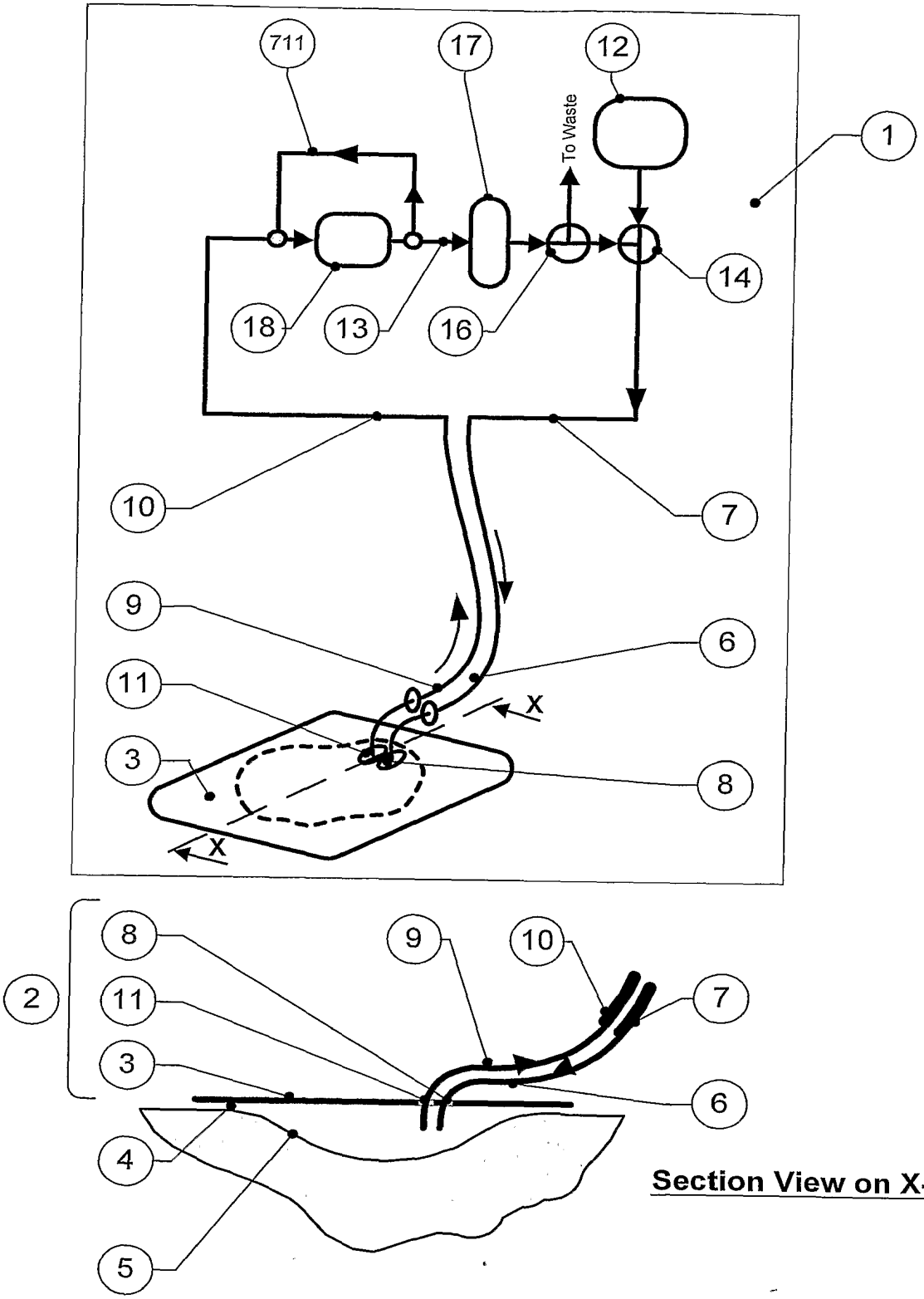


Figure 8b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Section View on X-X

Figure 9

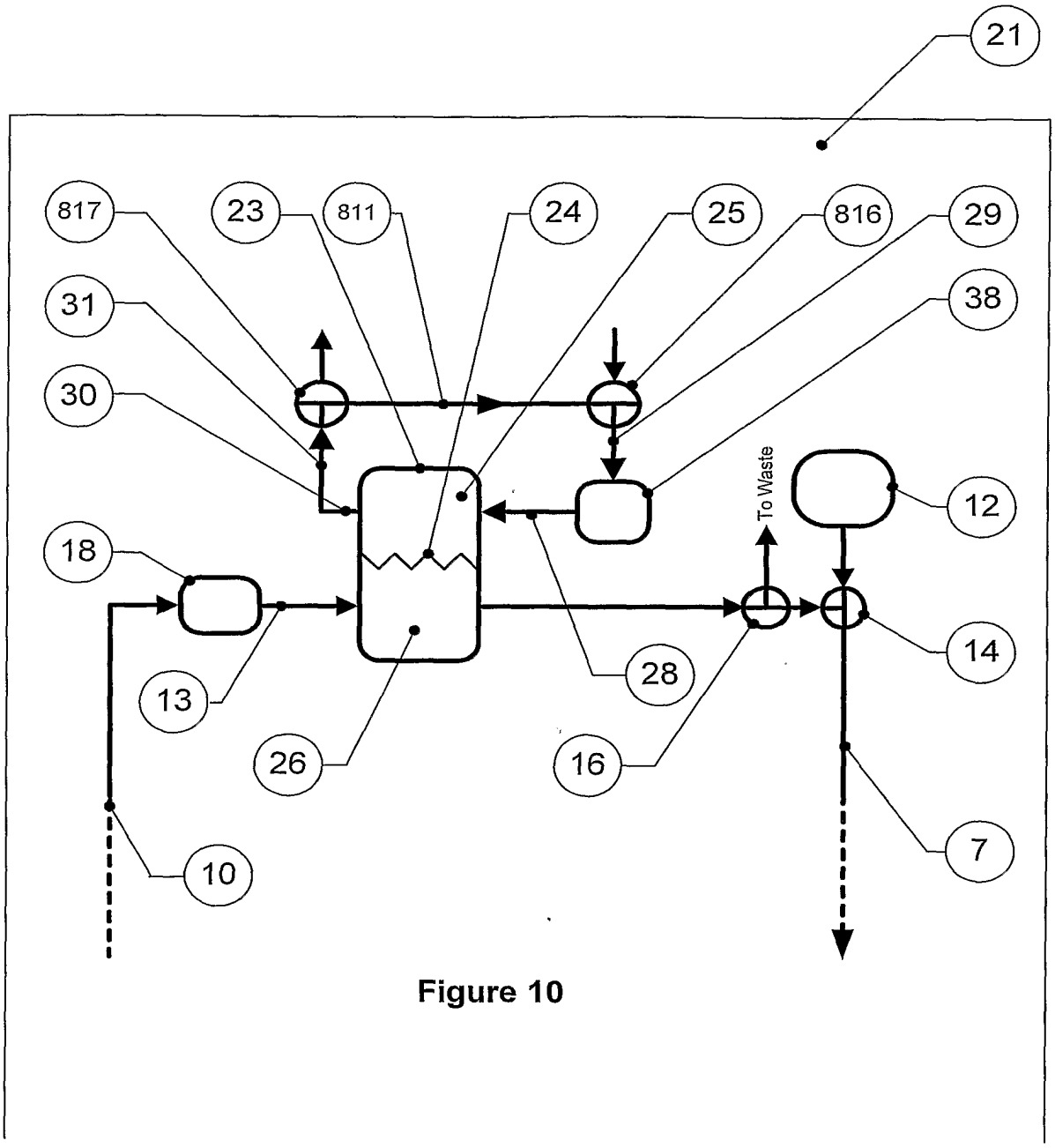

Figure 10

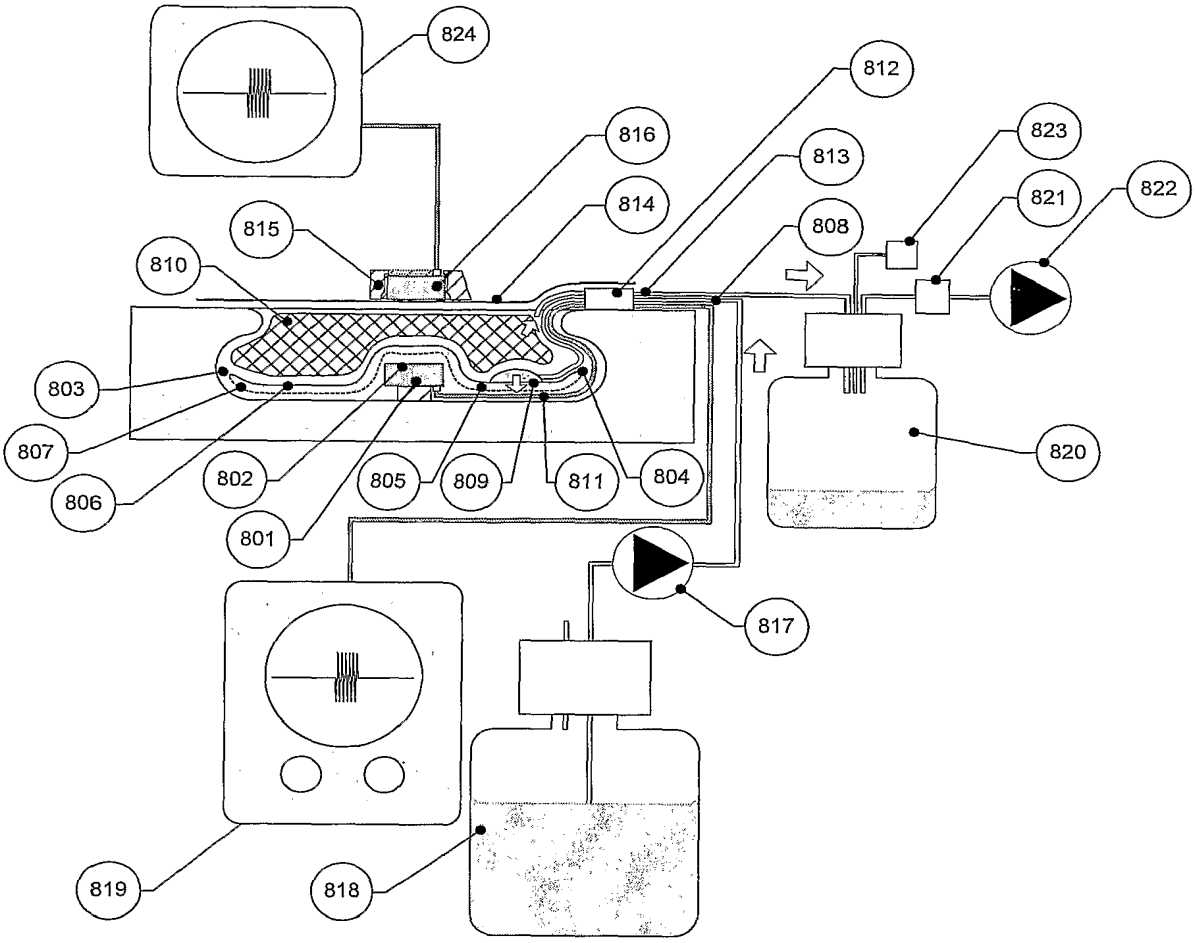
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Figure 12

INTERNATIONAL SEARCH REPORT

Int nal Application No
PCT/GB2005/001584

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M1/00 A61M3/02 A61M27/00 A61N7/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61N A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
E	WO 2005/051461 A (SMITH & NEPHEW PLC; BLOTT, PATRICK, LEWIS; GREENER, BRYAN; HARTWELL, E) 9 June 2005 (2005-06-09) page 15, line 21 - line 24 page 16, line 9 - line 13 page 30, line 19 - line 25 page 45, line 22 - line 25; figure 5	1-9
P,X	WO 2004/037334 A (SMITH & NEPHEW PLC; BLOTT, PATRICK, LEWIS; GREENER, BRYAN; HARTWELL, E) 6 May 2004 (2004-05-06) abstract page 31, line 23 - line 29	1-8
Y	WO 84/01904 A (SWANBECK, GUNNAR) 24 May 1984 (1984-05-24) page 2, last paragraph - page 3, paragraph 1; figure 1	1-9

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 August 2005	31/08/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Lakkis, A

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

Inte ıal Application No
PCT/GB2005/001584

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2003/171675 A1 (ROSENBERG LIOR) 11 September 2003 (2003-09-11) paragraphs '0003!, '0047! - '0052!; figure 1	1-9
A	WO 00/50143 A (NXSTAGE, INC) 31 August 2000 (2000-08-31) abstract	6-8

Form PCT/ISA/210 (continuation of second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2005/001584

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 10
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Inte Application No
PCT/GB2005/001584

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2005051461 A	09-06-2005	WO 2005051461 A1	09-06-2005
WO 2004037334 A	06-05-2004	AU 2003276408 A1	13-05-2004
		EP 1562668 A1	17-08-2005
		WO 2004037334 A1	06-05-2004
WO 8401904 A	24-05-1984	SE 445298 B	16-06-1986
		AU 2269583 A	04-06-1984
		DK 348984 A	17-07-1984
		EP 0142501 A1	29-05-1985
		NO 842896 A	16-07-1984
		SE 8206533 A	18-05-1984
		WO 8401904 A1	24-05-1984
US 2003171675 A1	11-09-2003	AT 297162 T	15-06-2005
		AU 8243801 A	18-02-2002
		DE 60111386 D1	14-07-2005
		EP 1304966 A1	02-05-2003
		JP 2004505660 T	26-02-2004
		WO 0211624 A1	14-02-2002
WO 0050143 A	31-08-2000	AU 3247300 A	14-09-2000
		WO 0050143 A1	31-08-2000
		US 6254567 B1	03-07-2001
		US 2001027289 A1	04-10-2001